



NATIONAL ASSEMBLY FOR WALES  
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STATUTORY INSTRUMENTS

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**2004 No. 478 (W.48)**

**NATIONAL HEALTH SERVICE, WALES**

The National Health Service (General Medical Services Contracts)  
(Wales) Regulations 2004

*Made*

*26th February 2004*

*Coming into force*

*1st March 2004*

**£10.50**





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**EXPLANATORY NOTE**

*(This note is not part of the Regulations)*

These Regulations set out, for Wales, the framework for general medical services contracts under section 28Q of the National Health Service Act 1977 ("the Act").

Part 2 of the Regulations prescribes the conditions which, in accordance with section 28S of the Act, must be met by a contractor before the Local Health Board may enter into a general medical services contract with it.

Part 3 of the Regulations prescribes the procedure for pre-contract dispute resolution, in accordance with section 28W(2) of the Act. Part 3 applies to cases where the contractor is not a health service body. In cases where the contractor is such a body, the procedure for dealing with pre-contract disputes is set out in section 4 of the National Health Service and Community Care Act 1990.

Part 4 of the Regulations sets out the procedures, in accordance with section 28W(3) of the Act, by which the contractor may obtain health service body status.

Part 5 of (and Schedules 2 to 6, and 8 to 10 to) the Regulations prescribe the terms which, in accordance with sections 28V and W of the Act, must be included in a general medical services contract (in addition to those contained in the Act). It includes, in regulation 15, a description of the services which must be provided to patients under general medical services contracts pursuant to section 28R of the Act.

The prescribed terms include terms relating to -

- (a) the type and duration of the contract (regulations 12 to 14);
- (b) the services to be provided (regulations 15, 16 and 18 to 20 and Schedule 2), the manner in which they are to be provided (Part 1 of Schedule 6) and the procedures for opting out of additional and out of hours services (regulation 17 and Schedule 3);
- (c) the issuing of medical certificates (regulation 21 and Schedule 4);
- (d) finance, fees and charges (regulations 22 to 24 and Schedule 5);
- (e) patient registration and removal, lists closures and assignments (Schedule 6, Part 2 and Schedule 8);
- (f) prescribing and dispensing (Schedule 6, Part 3);
- (g) the conditions to be met by those who perform services or are employed or engaged by the contractor (Schedule 6, Part 4);
- (h) patient records, the provision of information and rights of entry (Schedule 6, Part 5 and Schedule 10);
- (i) complaints (Schedule 6, Part 6);
- (j) procedures for dispute resolution (Schedule 6, Part 7); and

(k) procedures for variation and termination of contracts (Schedule 6, Part 8).

Part 6 of the Regulations prescribes functions for Local Medical Committees.

Part 7 of the Regulations and Schedule 7 make transitional provisions and provision for out of hours services.

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The National Assembly for Wales, in exercise of the powers conferred upon it by sections 28D(1)(bc), 28R, 28S, 28V, 28W, 45A(9) and 126(4) of the National Health Service Act 1977(a), and section 4(5) of the National Health Service and Community Care Act 1990(b) hereby makes the following Regulations:

## PART 1

### GENERAL

#### Citation, commencement and application

1.-(1) These Regulations may be cited as the National Health Service (General Medical Services Contracts) (Wales) Regulations 2004 and shall come into force on 1st March 2004.

(2) These Regulations apply in relation to Wales only.

#### Interpretation

2.-(1) In these Regulations -

"the Act" means the National Health Service Act 1977;

"the 1990 Act" means the National Health Service and Community Care Act 1990;

"the 2003 Order" means the General and Specialist Medical Practice (Education, Training and Qualifications) Order 2003(c);

"Abolition of the Tribunal Regulations" means the Abolition of the National Health Service Tribunal (Consequential Provisions) Regulations 2001(d);

"Abolition of the Tribunal (Wales) Regulations" means the Abolition of the National Health Service Tribunal (Consequential Provisions) Regulations 2002(e);

"additional services" means one or more of -

- (a) cervical screening services,
- (b) contraceptive services,
- (c) vaccinations and immunisations,
- (d) childhood vaccinations and immunisations,
- (e) child health surveillance services,
- (f) maternity medical services, and
- (g) minor surgery;

"adjudicator" means the Assembly or a person or persons appointed by the Assembly under section 4(5) of the 1990 Act or paragraph 101(5) of Schedule 6;

"appliance" means an appliance which is included in a list for the time being approved by the Assembly for the purposes of section 41 of the Act;

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- (a) 1977 c.49; section 28D(1)(bc) was inserted by section 177(2) of the Health and Social Care (Community Health and Standards) Act 2003 (c.43) ("the 2003 Act"); sections 28R, 28S, 28V and 28W were inserted by section 175(1) of that Act and section 45A by paragraph 23 of Schedule 11 to that Act.
  - (b) 1990 c.19.
  - (c) S.I. 2003/1250.
  - (d) S.I. 2001/3744 amended by S.I. 2002/2469.
  - (e) S.I. 2002/1920.

"approved medical practice" shall be construed in accordance with section 11(4) of the Medical Act 1983(a);

"Assembly" means the National Assembly for Wales;

"assessment panel" means a committee or sub-committee of a Local Health Board (other than the Local Health Board which is a party to the contract in question) appointed to exercise functions under paragraphs 31 and 35 of Schedule 6;

"bank holiday" means any day that is specified or proclaimed as a Bank holiday pursuant to section 1 of the Banking and Financial Dealings Act 1971(b);

"batch issue" means a form provided by a Local Health Board and issued by a prescriber at the same time as a repeatable prescription to enable a chemist to receive payment for the provision of repeat dispensing services which is in the format specified in Part 2 of Schedule 1, and which -

- (a) is generated by a computer and not signed by a prescriber,
- (b) relates to a particular repeatable prescription and contains the same dates as that prescription,
- (c) is issued as one of a sequence of forms, the number of which is equal to the number of occasions on which the drugs, medicines or appliances ordered on the repeatable prescription may be provided, and
- (d) specifies a number denoting its place in the sequence referred to in paragraph (c);

"CCT" means Certificate of Completion of Training awarded under article 8 of the 2003 Order, including any such certificate awarded in pursuance of the competent authority functions of the Postgraduate Medical Education and Training Board specified in article 20(3)(a) of that Order;

"cervical screening services" means the services described in paragraph 2(2) of Schedule 2;

"charity trustee" means one of the persons having the general control and management of a charity;

"chemist" means -

- (a) a registered pharmacist,
- (b) a person lawfully conducting a retail pharmacy business in accordance with section 69 of the Medicines Act 1968(c), or
- (c) a supplier of appliances,

who is included in the list of a Local Health Board or a Primary Care Trust under section 42 of the Act, or who provides local pharmaceutical services in accordance with LPS arrangements;

"CHC" means a Community Health Council retained or established under section 20A of the Act(d);

"child" means a person who has not attained the age of 16 years;

"child health surveillance services" means the services described in paragraph 6(2) of Schedule 2;

"childhood vaccinations and immunisations" means the services described in paragraph 5(2) of Schedule 2;

"closed", in relation to the contractor's list of patients, means closed to applications for inclusion in the list of patients other than from immediate family members of registered patients;

"contraceptive services" means the services described in paragraph 3(2) of Schedule 2;

"contract" means, except where the context otherwise requires, a general medical services contract under section 28Q of the Act;

"contractor's list of patients" means the list prepared and maintained by the Local Health Board under paragraph 14 of Schedule 6;

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(a) 1983 c.54; section 11(4) was amended by the National Health Service (Primary Care) Act 1997 (c.46), section 35(4) and Schedule 2, paragraph 61(2).

(b) 1971 c.80.

(c) 1968 c.67; section 69 was amended by the Statute Law (Repeals) Act 1993 (c.50) and the Pharmacists (Fitness to Practise) Act 1997 (c.19), Schedule 5, paragraph 5.

(d) Section 20A was inserted by section 1 of the Health (Wales) Act 2003 (c.4).

"core hours" means the period beginning at 8am and ending at 6.30pm on any day from Monday to Friday except Good Friday, Christmas Day or bank holidays;

"dispensing services" means the provision of drugs, medicines or appliances that may be provided as pharmaceutical services by a medical practitioner in accordance with arrangements made under regulation 20 of the Pharmaceutical Regulations;(a)

"Drug Tariff" has the same meaning as in regulation 18 of the Pharmaceutical Regulations;

"enhanced services" are -

- (a) services other than essential services, additional services or out of hours services, or
- (b) essential services, additional services or out of hours services or an element of such a service that a contractor agrees under the contract to provide in accordance with specifications set out in a plan, which requires of the contractor an enhanced level of service provision compared to that which it needs generally to provide in relation to that service or element of service;

"essential services" means the services required to be provided in accordance with regulation 15;

"FHSAA" means the Family Health Service Appeal Authority constituted under section 49S of the Act(b);

"general medical practitioner means -

- (a) from the coming into force of article 10 of the 2003 Order, a medical practitioner whose name is included in the General Practitioner Register otherwise than by virtue of paragraph 1(d) of Schedule 6 of that Order, and
- (b) until the coming into force of that article, a medical practitioner who is either -
  - (i) until the coming into force of paragraph 22 of Schedule 8 to the 2003 Order, suitably experienced within the meaning of section 31(2) of the Act, section 21 of the National Health Service (Scotland) Act 1978(c) or Article 8(2) of the Health and Personal Social Services (Northern Ireland) Order 1978(d); or
  - (ii) upon the coming into force of paragraph 22 of Schedule 8 to the 2003 Order, an eligible general practitioner pursuant to that paragraph other than by virtue of having an acquired right under paragraph 1(d) of Schedule 6 to the 2003 Order;

"General Practitioner Register" means the register kept by the General Medical Council under article 10 of the 2003 Order;

"global sum" has the same meaning as in the GMS Statement of Financial Entitlements;

"GMS Statement of Financial Entitlements" means the directions given by the Assembly under section 28T of the Act(e) on 1st April 2004;

"GP Registrar"-

- (a) until the coming into force of article 5 of the 2003 Order, means a medical practitioner who is being trained in general practice by a medical practitioner who-
  - (i) has been approved for that purpose by the Joint Committee on Postgraduate Training for General Practice under regulation 7 of the National Health Service (Vocational Training for General Medical Practice) Regulations 1997(f), and
  - (ii) performs primary medical services, and
- (b) from the coming into force of that article, means a medical practitioner who is being trained in general practice by a GP Trainer whether as part of training leading to the award of a CCT or otherwise;

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(a) Section 49S was inserted into the Act by section 27(1) of the Health and Social Care Act 2001 (c.15) ("the 2001 Act").

(b) 1978 c.29

(c) S.I. 1978/1907 (N.I. 26) or would have been so considered notwithstanding the repeal of the relevant provision.

(d) Section 28T was inserted into the Act by section 175 of the 2003 Act.

(e) S.I. 1997/2817 as amended by S.I. 1998/669.

(f) S.I 1972/1265 (N.I. 14).

"GP Trainer" means a general medical practitioner who is ?

- (a) until the coming into force of article 4(5)(d) of the 2003 Order, approved as a GP Trainer by the Joint Committee on Postgraduate Training for General Practice under regulation 7 of the National Health Service (Vocational Training for General Medical Practice) Regulations 1997; or
- (b) from the coming into force of that article, approved by the Postgraduate Medical Education and Training Board under article 4(5)(d) of the 2003 Order for the purposes of providing training to a GP Registrar under article 5(1)(c)(i);

"Health and Social Services Board" means a Health and Social Services Board established under the Health and Personal Social Services (Northern Ireland) Order 1972(a);

"Health and Social Services Trust" means a Health and Social Services Trust established under Article 10(1) of the Health and Personal Social Services (Northern Ireland) Order 1991(b);

"Health Board" means a Health Board established under section 2 of the National Health Service (Scotland) Act 1978(c);

"health care professional" has the same meaning as in section 28M of the Act and "health care profession" shall be construed accordingly;

"health service body" has, unless the context otherwise requires, the meaning given to it in section 4(2) of the 1990 Act;

"immediate family member" means -

- (a) a spouse,
- (b) a person (whether or not of the opposite sex) whose relationship with the registered patient has the characteristics of the relationship between husband and wife,
- (c) a parent or step-parent,
- (d) a son,
- (e) a daughter,
- (f) a child of whom the registered patient is -
  - (i) the guardian, or
  - (ii) the carer duly authorised by a local authority to whose care the child has been committed under the Children Act 1989(d), or
- (g) a grandparent;

"independent nurse prescriber" means a person-

- (a) who is either engaged or employed by the contractor or is a party to the contract,
- (b) who is registered in the Nursing and Midwifery Register, and
- (c) in respect of whom an annotation signifying that he or she is qualified to order drugs, medicines and appliances from-
  - (i) the Nurse Prescribers' Formulary for District Nurses and Health Visitors in Part XVIIB(i) of the Drug Tariff, or
  - (ii) the Nurse Prescribers' Extended Formulary in Part XVIIB(ii) of the Drug Tariff,

is also included in that register;

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(a) S.I. 1991/194 (N.I. 1).

(b) 1978 c.29.

(c) Section 4(2) was amended by the Health Authorities Act 1995 (c.17) Schedule 1, paragraph 68, the Health Act 1999 (c.8), Schedule 4, paragraph 76(a) and Schedule 5, the National Health Service Reform and Health Care Professions Act 2002 (c.17), Schedule 1, paragraph 40, and Schedule 5, paragraph 31.

(d) 1989 c.41.

"licensing authority" shall be construed in accordance with section 6(3) of the Medicines Act 1968(a);

"licensing body" means any body that licenses or regulates any profession;

"limited partnership" means a partnership registered in accordance with section 5 of the Limited Partnerships Act 1907(b);

"Local Health Board" means, unless the context otherwise requires, the Local Health Board which is a party, or prospective party, to the contract(c);

"Local Medical Committee" means a committee recognised under section 45A of the Act;

"local pharmaceutical services" has the same meaning as in regulation 2 of the National Health Service (Local Pharmaceutical Services and Pharmaceutical Services) Regulation 2002(d).

"maternity medical services" means the services described in paragraph 7(1) of Schedule 2;

"medical card" means a card issued by a Local Health Board, Primary Care Trust, Health Authority, Health Board or Health and Social Services Board to a person for the purpose of enabling him to obtain, or establishing his title to receive, primary medical services;

"medical officer" means a medical practitioner who is -

- (a) employed or engaged by the Department for Work and Pensions, or
- (b) provided by an organisation in pursuance of a contract entered into with the Secretary of State for Work and Pensions;

"medical performers list" means a list of medical practitioners prepared in accordance with regulations made under section 28X of the Act(e);

"Medical Register" means the registers kept under section 2 of the Medical Act 1983(f);

"minor surgery" means the services described in paragraph 8(2) of Schedule 2;

"NCAA" means the National Clinical Assessment Authority established as a Special Health Authority under section 11 of the Act;

"national disqualification" means -

- (a) a decision made by the FHSAA under section 49N of the Act,
- (b) a decision under provisions in force in Scotland or Northern Ireland corresponding to section 49N of the Act, or
- (c) a decision by the NHS Tribunal which is treated as a national disqualification by the FHSAA by virtue of regulation 6(4)(b) of the Abolition of the Tribunal Regulations or regulation 6(4)(b) of the Abolition of the Tribunal (Wales) Regulations;

"NHS contract" has the meaning assigned to it in section 4 of the 1990 Act;

"the NHS dispute resolution procedure" means the procedure for resolution of disputes specified -

- (a) in paragraphs 99 and 100 of Schedule 6; or
- (b) in a case to which paragraph 36 of Schedule 6 applies, in that paragraph.

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(a) 1968 c.67.

(b) 1907 c.24.

(c) Local Health Boards were established under section 16BA of the Act; SI 2003/148 (W.18)

(d) 1989 c.41.

(e) Section 28X was inserted into the Act by section 179(1) of the 2003 Act.

(f) 1983 c. 54; section 2 was amended by S.I. 1996/1591 and 2002/3135.



"the NHS Tribunal" means the Tribunal constituted under section 46 of the Act(a) for England and Wales, and which, except for prescribed cases, had effect in relation to England only until 14th December 2001 and in relation to Wales only until 26th August 2002(b);

"normal hours" means those days and hours on which and the times at which services under the contract are normally made available and may be different for different services;

"Nursing and Midwifery Register" means the register maintained by the Nursing and Midwifery Council under the Nursing and Midwifery Order 2001(c);

"open", in relation to a contractor's list of patients, means open to applications from patients in accordance with paragraph 15 of Schedule 6;

"out of hours period" means -

- (a) the period beginning at 6.30pm on any day from Monday to Thursday and ending at 8am on the following day;
- (b) the period between 6.30pm on Friday and 8am on the following Monday, and
- (c) Good Friday, Christmas Day and bank holidays,

and "part" of an out of hours period means any part of any one or more of periods described in paragraphs (a) to (c);

"out of hours services" means services required to be provided in all or part of the out of hours period which -

- (a) would be essential services if provided in core hours, and
- (b) are included in the contract as additional services funded under the global sum;

"parent" includes, in relation to any child, any adult who, in the opinion of the contractor, is for the time being discharging in respect of that child the obligations normally attaching to a parent in respect of his or her child;

"patient" means -

- (a) a registered patient,
- (b) a temporary resident,
- (c) persons to whom the contractor is required to provide immediately necessary treatment under regulation 15(6) or (8) respectively,
- (d) any other person to whom the contractor has agreed to provide services under the contract,
- (e) any person for whom the contractor is responsible under regulation 31, and
- (f) any person for whom the contractor is responsible under arrangements made with another contractor in accordance with Schedule 7;

"Pharmaceutical Regulations" means the National Health Service (Pharmaceutical Services) Regulations 1992(d);

"pilot scheme" means an agreement made under Part 1 of the National Health Service (Primary Care) Act 1997(e);

"the POM Order" means the Prescription Only Medicines (Human Use) Order 1997(f);

"practice" means the business operated by the contractor for the purpose of delivering services under the contract;

"practice area" means the area referred to in regulation 18(1)(d);

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(a) Section 46 was revoked by the 2001 Act, section 67, Schedule 5, paragraphs 5 and Schedule 6, Part 1.

(b) See S.I. 2001/3738, article 2(5) and (6)(b), which sets out the prescribed cases for England and S.I. 2002/1919, article 2(2) and (3)(b), which sets out the prescribed cases for Wales.

(c) S.I. 2002/253.

(d) S.I. 1992/662 as amended by S.I. 1993/2451, 1994/2402, 1995/644, 1996/698, 1998/681, 1999/696 and 2563, 2000/593, 2001/1396 and 2888, 2002/551, 888, 2016, 2469 and 2861 and 2003/699 and 1084.

(e) 1997 (c.46).

(f) S.I. 1997/1830 as amended by S.I. 1997/2044, 1998/108, 1178 and 2081, 1999/1044 and 3463, 2000/1917, 2889 and 3231, 2001/2777, 2889 and 3942, 2002/549 and 2469 and 2003/696.

"practice leaflet" means a leaflet drawn up in accordance with paragraph 75 of Schedule 6;

"practice premises" means an address specified in the contract as one at which services are to be provided under the contract;

"prescriber" means -

- (a) a medical practitioner,
- (b) an independent nurse prescriber, and
- (c) a supplementary prescriber,

who is either engaged or employed by the contractor or is a party to the contract;

"prescription form" means a form provided by the Local Health Board and issued by a prescriber to enable a person to obtain pharmaceutical services or local pharmaceutical services and does not include a repeatable prescription;

"prescription only medicine" means a medicine referred to in article 3 of the POM Order (medicinal products on prescription only);

"primary care list" means -

- (a) a list of persons performing primary medical or dental services prepared in accordance with regulations made under section 28X of the Act<sup>(a)</sup>,
- (b) a list of persons undertaking to provide general medical services, general dental services, general ophthalmic services or, as the case may be, pharmaceutical services prepared in accordance with regulations made under sections 29, 36, 39, 42 or 43 of the Act,
- (c) a list of persons approved for the purposes of assisting in the provision of any services mentioned in paragraph (b) prepared in accordance with regulations made under section 43D of the Act<sup>(b)</sup>,
- (d) a services list referred to in section 8ZA of the National Health Service (Primary Care) Act 1997<sup>(c)</sup>,
- (e) a list corresponding to a services list prepared by virtue of regulations made under section 41 of the Health and Social Care Act 2001<sup>(d)</sup>, or
- (f) a list corresponding to any of the above lists in Scotland or Northern Ireland;

"Primary Care Trust" means, a Primary Care Trust established under section 16A of the Act;

"primary carer" means, in relation to an adult, the adult or organisation primarily caring for that adult;

"registered patient" means -

- (a) a person who is recorded by the Local Health Board as being on the contractor's list of patients, or
- (b) a person whom the contractor has accepted for inclusion on its list of patients, whether or not notification of that acceptance has been received by the Local Health Board and who has not been notified by the Local Health Board as having ceased to be on that list;

"relevant register" means -

- (a) in relation to a nurse, the Nursing and Midwifery Register, and
- (b) in relation to a pharmacist, the register maintained in pursuance of section 2(1) of the Pharmacy Act 1954<sup>(e)</sup> or the register maintained in pursuance of Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976<sup>(f)</sup>;

"repeat dispensing services" means pharmaceutical services or local pharmaceutical services which involve the provision of drugs, medicines or appliances by a chemist in accordance with a repeatable prescription;

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(a) Section 28X was inserted into the Act by section 179(1) of the 2003 Act.

(b) Section 43D was inserted into the Act by section 24 of the 2001 Act.

(c) 1997 c.46. Section 8ZA was inserted into that Act by section 26(2) of the 2001 Act.

(d) 2001 c.15.

(e) 1954 c.61.

(f) S.I. 1976/1213 (N.I. 22).

"repeatable prescribing services" means services which involve the prescribing of drugs, medicines or appliances on a repeatable prescription;

"repeatable prescription" means a prescription contained in a form provided by a Local Health Board and issued by a prescriber to enable a person to obtain pharmaceutical services or local pharmaceutical services, which is in the format specified in Part 1 of Schedule 1 and which -

- (a) is generated by a computer but signed by a prescriber, and
- (b) indicates that the drugs, medicines or appliances ordered on that form may be provided more than once and specifies the number of occasions on which they may be provided;

"restricted availability appliance" means an appliance which is approved for particular categories of persons or particular purposes only;

"Scheduled drug" means -

- (a) a drug, medicine or other substance specified in any directions given by the Assembly under section 28U of the Act(a) as being a drug, medicine or other substance which may not be ordered for patients in the provision of medical services under the contract, or
- (b) except where the conditions in paragraph 42(2) of Schedule 6 are satisfied, a drug, medicine or other substance which is specified in any directions given by the Assembly under section 28U of the Act as being a drug, medicine or other substance which can only be ordered for specified patients and specified purposes;

"section 28C provider" means a person who is providing services under a pilot scheme or in accordance with section 28C arrangements;

"supplementary prescriber" means a person -

- (a) who is either engaged or employed by the contractor or is a party to the contract,
- (b) whose name is registered in -
  - (i) the Nursing and Midwifery Register,
  - (ii) the Register of Pharmaceutical Chemists maintained in pursuance of section 2(1) of the Pharmacy Act 1954, or
  - (iii) the register maintained in pursuance of Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976, and
- (c) and against whose name is recorded in the relevant register an annotation signifying that he or she is qualified to order drugs medicines and appliances as a supplementary prescriber;

"temporary resident" means a person accepted by the contractor as a temporary resident under paragraph 16 of Schedule 6 and for whom the contractor's responsibility has not been terminated in accordance with that paragraph;

"walk-in centre" means a centre at which information and treatment for minor conditions is provided to the public under arrangements made by or on behalf of the Assembly;

"working day" means any day apart from Saturday, Sunday, Christmas Day, Good Friday or a bank holiday;

"writing", except in paragraph 102(1) of Schedule 6 and unless the context otherwise requires, includes electronic mail and "written" shall be construed accordingly.

(2) In these Regulations, the use of the term "it" in relation to the contractor shall be deemed to include a reference to a contractor that is an individual medical practitioner or two or more individuals practising in partnership and related expressions shall be construed accordingly.

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(a) Section 28U was inserted into the Act by section 171 of the 2003 Act. The current directions are.....

## PART 2

### CONTRACTORS

3. Subject to the provisions of any order made by the Assembly under section 176 of the Health and Social Care (Community Health and Standards) Act 2003 (general medical services : transitional) a Local Health Board may only enter into a contract if the conditions set out in regulations 4 and 5 are met.

#### Conditions : General

4.-(1) In the case of a contract to be entered into with a medical practitioner, that practitioner must be a general medical practitioner.

(2) In the case of a contract to be entered into with two or more individuals practising in partnership -

(a) at least one partner (who must not be a limited partner) must be a general medical practitioner; and

(b) any other partner who is a medical practitioner must -

(i) be a general medical practitioner, or

(ii) be employed by a Local Health Board, Primary Care Trust, (in England and Wales and Scotland) NHS Trust, an NHS foundation trust, (in Scotland) a Health Board or (in Northern Ireland) a Health and Social Services Trust.

(3) In the case of a contract to be entered into with a company limited by shares -

(a) at least one share in the company must be legally and beneficially owned by a general medical practitioner; and

(b) any other share or shares in the company that are legally and beneficially owned by a medical practitioner must be so owned by -

(i) a general medical practitioner, or

(ii) a medical practitioner who is employed by a Local Health Board, a Primary Care Trust, (in England and Wales and Scotland) a NHS Trust, a NHS foundation trust, (in Scotland) a Health Board or (in Northern Ireland) a Health and Social Services Trust.

#### General condition relating to all contracts

5.-(1) It is a condition in the case of a contract to be entered into -

(a) with a medical practitioner, that the medical practitioner;

(b) with two or more individuals practising in partnership, that any individual or the partnership; and

(c) with a company limited by shares that -

(i) the company,

(ii) any person legally and beneficially owning a share in the company, and

(iii) any director or secretary of the company,

must not fall within paragraph (2).

(2) A person falls within this paragraph if -

(a) he, she or it is the subject of a national disqualification;

(b) subject to paragraph (3), he, she or it is disqualified or suspended (other than by an interim suspension order or direction pending an investigation) from practising by any licensing body anywhere in the world;

(c) within the period of five years prior to the signing of the contract or commencement of the contract, whichever is the earlier, he or she has been dismissed (otherwise than by reason of redundancy) from any employment by a health service body and paragraph (4) applies to him or her unless he or she has subsequently been employed by that health service body or another health service body or that dismissal was the subject of a finding of unfair dismissal by any competent tribunal or court;

(d) within the period of five years prior to signing the contract or commencement of the contract, whichever

is the earlier, he, she or it has been removed from, or refused admission to, a primary care list by reason of inefficiency, fraud or unsuitability (within the meaning of section 49F(2), (3) and (4) of the Act respectively) unless his or her name has subsequently been included in such a list;

- (e) he or she has been convicted in the United Kingdom of murder;
- (f) he or she has been convicted in the United Kingdom of a criminal offence other than murder, committed on or after 26th August 2002, and has been sentenced to a term of imprisonment of over six months;
- (g) subject to paragraph (5) he or she has been convicted elsewhere of an offence
  - (i) which would, if committed in England and Wales, constitute murder; or
  - (ii) committed on or after 26th August 2002, which would if committed in England and Wales constitute a criminal offence other than murder, and had been sentenced to a term of imprisonment of over six months;
- (h) he or she has been convicted of an offence referred to in Schedule 1 to the Children and Young Persons Act 1933(a) (offences against children and young persons with respect to which special provisions of this Act apply) or Schedule 1 to the Criminal Procedure Act (Scotland) 1995 (offences against children under the age of 17 years to which special provisions apply)(b) committed on or after 1st March 2004.
- (i) he, she or it has been -
  - (i) adjudged bankrupt or had sequestration of his or her estate awarded unless (in either case) he or she has been discharged or the bankruptcy order has been annulled;
  - (ii) made the subject of a bankruptcy restrictions order or an interim bankruptcy restrictions order under Schedule 4A to the Insolvency Act 1986(c) unless that order has ceased to have effect or has been annulled, or
  - (iii) made a composition or arrangement with, or granted a trust deed for, his, her or its creditors unless he, she or it has been discharged in respect of it;
- (j) he or she has been -
  - (i) removed from the office of charity trustee or trustee for a charity by an order made by the Charity Commissioners or the High Court on the grounds of any misconduct or mismanagement in the administration of the charity for which he or she was responsible or to which he or she was privy, or which he or she by his or her conduct contributed to or facilitated, or
  - (ii) removed under section 7 of the Law Reform (Miscellaneous Provisions) (Scotland) Act 1990(d) (powers of the Court of Session to deal with management of charities), from being concerned in the management or control of any body; or
- (k) he or she is subject to a disqualification order under the Company Directors Disqualification Act 1986(e), the Companies (Northern Ireland) Order 1986(f) or to an order made under section 429(2)(b) of the Insolvency Act 1986(g) (failure to pay under county court administration order).

(3) A person shall not fall within paragraph (2)(b) where the Local Health Board is satisfied that the disqualification or suspension from practising is imposed by a licensing body outside the United Kingdom and it does not make the person unsuitable to be -

- (a) a contractor;
- (b) a partner, in the case of a contract with two or more individuals practising in partnership;
- (c) in the case of a contract with a company limited by shares?
  - (i) a person legally and beneficially holding a share in the company, or
  - (ii) a director or secretary of the company,

as the case may be.

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(a) 1933 c 12 as amended by the Criminal Justice Act 1988 ( c.33), section 170, Schedule 15, paragraph 8 and Schedule 16, paragraph 16; Sexual Offences Act 1956 (c.69), sections 48 and 51 and Schedules 3 and 4 and as modified by the Criminal Justice Act 1988, section 170(1), Schedule 15, paragraph 9.

(b) 1995 c.46.

(c) 1986 c.45 Schedule 4A was inserted by section 257 of and Schedule 20 to the Enterprise Act 2002 (c.40).

(d) 1990 c.40.

(e) 1986 c.46 as amended by the Insolvency Act 2000 (c.39).

(f) S.I.1986/1032 (N.1.6).

(g) 1986 c.45.

(4) Where a person has been employed as a member of a health care profession any subsequent employment must also be as a member of that profession if the exception in paragraph(2)(c) is to apply to him or her.

(5) A person shall not fall within paragraph (2)(g) where the Local Health Board is satisfied that the conviction does not make the person unsuitable to be ?

(a) a contractor;

(b) a partner, in the case of a contract with two or more individuals practising in partnership;

(c) in the case of a contract with a company limited by shares ?

(i) a person legally and beneficially holding a share in the company, or

(ii) a director or secretary of the company,

as the case may be.

### **Reasons**

6.-(1) Where a Local Health Board is of the view that the conditions in regulation 4 or 5 for entering into a contract are not met it shall notify in writing the person or persons intending to enter into the contract of its view and its reasons for that view and of his, her or its or their right of appeal under regulation 7.

(2) The Local Health Board shall also notify in writing of its view and its reasons for that view, if any person legally and beneficially owning a share in, or a director or secretary of, a company that is notified under paragraph (1) where its reason for the decision relates to that person or those persons.

### **Appeal**

7. A person who has been served with a notice under regulation 6(1) may appeal to the FHSAA against the decision of the Local Health Board that the conditions in regulation 4 or 5 are not met by giving notice in writing to the FHSAA within the period of 28 days beginning on the day that the Local Health Board served its notice.

### **Prescribed period under section 28D(1)(bc) of the Act**

8. The period prescribed for the purposes of section 28D(1)(bc) of the Act (persons with whom agreements may be made) is six months.

## **PART 3**

### **PRE-CONTRACT DISPUTE RESOLUTION**

#### **Pre-contract disputes**

9.-(1) Except where both parties to the prospective contract are health service bodies (in which case section 4(4) of the 1990 Act (NHS contracts) applies) if, in the course of negotiations intending to lead to a contract, the prospective parties to that contract are unable to agree on a particular term of the contract, either party may refer the dispute to the Assembly to consider and determine the matter.

(2) Disputes referred to the Assembly in accordance with paragraph (1) or section 4(4) of the 1990 Act shall be considered and determined in accordance with the provisions of paragraphs 99(3) to (14) and 100(1) of Schedule 6, and paragraph (3) (where it applies) of this regulation.

(3) In the case of a dispute referred to the Assembly under paragraph (1), the determination -

(a) may specify terms to be included in the proposed contract;

(b) may require the Local Health Board to proceed with the proposed contract, but may not require the proposed contractor to proceed with the proposed contract; and

(c) shall be binding upon the prospective parties to the contract.

## PART 4

### HEALTH SERVICE BODY STATUS

#### Health service body status

**10.**-(1) Where a proposed contractor elects in a written notice served on the Local Health Board at any time prior to the contract being entered into to be regarded as a health service body for the purposes of section 4 of the 1990 Act, it shall be so regarded from the date on which the contract is entered into.

(2) If, pursuant to paragraph (1) or (5) a contractor is to be regarded as a health service body that fact, it shall not affect the nature of, or any rights or liabilities arising under, any other contract with a health service body entered into by a contractor before the date on which the contractor is to be so regarded.

(3) Where a contract is made with an individual medical practitioner or two or more persons practising in partnership, and that individual, or that partnership is to be regarded as a health service body in accordance with paragraph (1) or (5) the contractor shall subject to paragraph (4) continue to be regarded as a health service body for the purposes of section 4 of the 1990 Act for as long as that contract continues irrespective of any change in ?

- (a) the partners comprising the partnership;
- (b) the status of the contractor from that of an individual medical practitioner to that of a partnership; or
- (c) the status of the contractor from that of a partnership to that of an individual medical practitioner

(4) A contractor may at any time request in writing a variation of the contract to include provision in or remove provision from the contract that the contract is an NHS contract, and if it does so -

- (a) the Local Health Board shall agree to the variation; and
- (b) the procedure in paragraph 102(1) of Schedule 6 shall apply.

(5) If, pursuant to paragraph (4), the Local Health Board agrees to the variation to the contract, the contractor shall -

- (a) be regarded; or
- (b) subject to paragraph (7), cease to be regarded,

as a health service body for the purposes of section 4 of the 1990 Act from the date that variation is to take effect pursuant to paragraph 102(1) of Schedule 6.

(6) Subject to paragraph (7), a contractor shall cease to be a health service body for the purposes of section 4 of the 1990 Act if the contract terminates.

(7) Where a contractor ceases to be a health service body pursuant to ?

- (a) paragraph (5) or (6), it shall continue to be regarded as a health service body for the purposes of being a party to any other NHS contract entered into after it became a health service body but before the date on which the contractor ceased to be a health service body (for which purpose it ceases to be such a body on the termination of that NHS contract);
- (b) paragraph (5), it shall, if it or the Local Health Board has referred any matter to the NHS dispute resolution procedure before it ceases to be a health service body, be bound by the determination of the adjudicator as if the dispute had been referred pursuant to paragraph 98 of Schedule 6;
- (c) paragraph (6), it shall continue to be regarded as a health service body for the purposes of the NHS dispute resolution procedure where that procedure has been commenced-
  - (i) before the termination of the contract, or
  - (ii) after the termination of the contract, whether in connection with or arising out of the termination of the contract or otherwise,

for which purposes it ceases to be such a body on the conclusion of that procedure.

## PART 5

### CONTRACTS: REQUIRED TERMS

#### Parties to the contract

11. A contract must specify -

- (a) the names of the parties;
- (b) in the case of a partnership -
  - (i) whether or not it is a limited partnership, and
  - (ii) the names of the partners and, in the case of a limited partnership, their status as a general or limited partner; and
- (c) in the case of each party, the address to which official correspondence and notices should be sent.

#### Health service contract

12. If the contractor is to be regarded as a health service body pursuant to regulation 10, the contract must state that it is an NHS contract.

#### Contracts with individuals practising in partnership

13.-(1) Where the contract is with two or more individuals practising in partnership, the contract shall be treated as made with the partnership as it is from time to time constituted, and the contract shall make specific provision to this effect.

(2) Where the contract is with two or more individuals practising in partnership, the contractor must be required by the terms of the contract to ensure that any person who becomes a member of the partnership after the contract has come into force is bound automatically by the contract whether by virtue of a partnership deed or otherwise.

#### Duration

14.-(1) Except in the circumstances specified in paragraph (2), a contract must provide for it to subsist until it is terminated in accordance with the terms of the contract or the general law.

(2) The circumstances referred to in paragraph (1) are that the Local Health Board wishes to enter into a temporary contract for a period not exceeding twelve months for the provision of services to the former patients of a contractor, following the termination of that contractor's contract.

(3) Either party to a prospective contract to which paragraph (2) applies may, if it wishes to do so, invite the Local Medical Committee for the area of the Local Health Board to participate in the negotiations intending to lead to such a contract.

#### Essential services

15.-(1) For the purposes of section 28R(1) of the Act (requirement to provide certain primary medical services), the services which must be provided under a general medical services contract ("essential services") are the services described in paragraphs (3), (5), (6) and (8).

(2) Subject to regulation 20, a contractor must provide the services described in paragraphs (3) and (5) throughout the core hours.

(3) The services described in this paragraph are services required for the management of its registered patients and temporary residents who are or believe themselves to be -

- (a) ill, with conditions from which recovery is generally expected;
- (b) terminally ill; or
- (c) suffering from chronic disease,



delivered in the manner determined by the practice in discussion with the patient.

(4) For the purposes of paragraph (3) -

"disease" means a disease included in the list of three-character categories contained in the tenth revision of the International Statistical Classification of Diseases and Related Health Problems(a); and

"management" includes -

- (a) offering consultation and, where appropriate, physical examination for the purpose of identifying the need, if any, for treatment or further investigation; and
- (b) the making available of such treatment or further investigation as is necessary and appropriate, including the referral of the patient for other services under the Act and liaison with other health care professionals involved in the patient's treatment and care.

(5) The services described in this paragraph are the provision of appropriate ongoing treatment and care to all registered patients and temporary residents taking account of their specific needs including -

- (a) the provision of advice in connection with the patient's health, including relevant health promotion advice; and
- (b) the referral of the patient for other services under the Act.

(6) A contractor must provide primary medical services required in core hours for the immediately necessary treatment of any person to whom the contractor has been requested to provide treatment owing to an accident or emergency at any place in its practice area.

(7) In paragraph (6), "emergency" includes any medical emergency whether or not related to services provided under the contract.

(8) A contractor must provide primary medical services required in core hours for the immediately necessary treatment of any person falling within paragraph (9) who requests such treatment, for the period specified in paragraph (10).

(9) A person falls within paragraph (8) if he or she is a person -

- (a) whose application for inclusion in the contractor's list of patients has been refused in accordance with paragraph 17 of Schedule 6 and who is not registered with another provider of essential services (or their equivalent) in the area of the Local Health Board;
- (b) whose application for acceptance as a temporary resident has been rejected under paragraph 17 of Schedule 6; or
- (c) who is present in the contractor's practice area for less than 24 hours.

(10) The period referred to in paragraph (8) is -

- (a) in the case of paragraph (9)(a), 14 days beginning with the date on which that person's application was refused or until that person has been subsequently registered elsewhere for the provision of essential services (or their equivalent), whichever occurs first;
- (b) in the case of paragraph (9)(b), 14 days beginning with the date on which that person's application was rejected or until that person has been subsequently accepted elsewhere as a temporary resident, whichever occurs first; and
- (c) in the case of paragraph (9)(c), 24 hours or such shorter period as the person is present in the contractor's practice area.

### **Additional services**

**16.** A contract which includes the provision of any additional services must-

- (a) in relation to all such services as are included in the contract, contain a term which has the same effect as that specified in paragraph 1 of Schedule 2; and
- (b) in relation to each such service as is included in the contract, contain terms which have the same effect as those specified in Schedule 2 which are relevant to that service.

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(a) World Health Organisation, 1992 ISBN 92 4 1544 19 8 (v. I) NLM Classification: WB 15.

## **Opt outs of additional and out of hours services**

17.-(1) Where a contract provides for the contractor to provide an additional service that is to be funded through the global sum the contract must contain terms relating to the procedure for opting out of additional services which have the same effect as those specified in paragraphs 1, 2, 3 and 6 of Schedule 3 except paragraph 3(12) to (14).

(2) Where a contract which is entered into before 1st October 2004 provides for the contractor to provide out of hours services pursuant to regulation 30 or 31, the contract must contain terms relating to the procedure for opting out of those services which have the same effect as those specified in paragraphs 4, 5 and 6 of Schedule 3, except paragraphs 4(8) and 5(17) in so far as those paragraphs relate to paragraph 3(12) to (14).

(3) Where a contract which is entered into on or after 1st October 2004 provides for the contractor to provide out of hours services pursuant to regulation 30 or 31, the contract must contain terms relating to the procedure for opting out of those services which have the same effect as those specified in paragraphs 4 and 6 of Schedule 3, except paragraph 4(8) in so far as those paragraphs relate to paragraph 3(12) to (14).

(4) Paragraph 3(12) to (14) and paragraphs 4(8) and 5(17) in so far as those paragraphs relate to paragraph 3(12) to (14) of Schedule 3 shall have effect in relation to the matters set out in those paragraphs.

## **Services generally**

18.-(1) A contract must specify -

- (a) the services to be provided;
- (b) subject to paragraph (2), the address of each of the premises to be used by the contractor or any sub-contractor for the provision of such services;
- (c) to whom such services are to be provided;
- (d) the area as respects which persons resident in it will, subject to any other terms of the contract relating to patient registration, be entitled to -
  - (i) register with the contractor, or
  - (ii) seek acceptance by the contractor as a temporary resident; and
- (e) whether, at the date on which the contract comes into force, the contractor's list of patients is open or closed.

(2) The premises referred to in paragraph (1)(b) do not include -

- (a) the homes of patients; or
- (b) any other premises where services are provided on an emergency basis.

(3) Where, on the date on which the contract is signed, the Local Health Board is not satisfied that all or any of the premises specified in accordance with paragraph (1)(b) meet the requirements set out in paragraph 1 of Schedule 6, the contract must include a plan, drawn up jointly by the Local Health Board and the contractor, which specifies-

- (a) the steps to be taken by the contractor to bring the premises up to the relevant standard;
- (b) any financial support that may be available from the Local Health Board; and
- (c) the timescale on which the steps referred to in sub-paragraph (a) will be taken.

(4) Where, in accordance with paragraph (1)(e), the contract specifies that the contractor's list of patients is closed it must also specify in relation to that closure each of the items listed in paragraph 29(8)(a) to (d) of Schedule 6.

19.-(1) Except in the case of the services referred to in paragraph (2), the contract must state the period (if any) for which the services are to be provided.

(2) The services referred to in paragraph (1) are -

- (a) essential services;
- (b) additional services funded under the global sum; and
- (c) out of hours services provided pursuant to regulations 30 and 31.

20. A contract must contain a term which requires the contractor in core hours -

- (a) to provide-

- (i) essential services, and
- (ii) additional services funded under the global sum,

at such times, within core hours, as are appropriate to meet the reasonable needs of its patients; and

- (b) to have in place arrangements for its patients to access such services throughout the core hours in case of emergency.

### **Certificates**

**21.**-(1) A contract must contain a term which has the effect of requiring the contractor to issue free of charge to a patient or the patient's personal representatives any medical certificate of a description prescribed in column 1 of Schedule 4, which is reasonably required under or for the purposes of the enactments specified in relation to the certificate in column 2 of that Schedule, except where, for the condition to which the certificate relates, the patient -

- (a) is being attended by a medical practitioner who is not -
  - (i) employed or engaged by the contractor;
  - (ii) in the case of a contract with two or more individuals practising in partnership, one of those individuals; or
  - (iii) in the case of a contract with a company limited by shares, one of the persons legally or beneficially owning shares in that company; or
- (b) is not being treated by or under the supervision of a health care professional.

(2) The exception in paragraph (1)(a) shall not apply where the certificate is issued pursuant to regulation 2(1)(b) of the Social Security (Medical Evidence) Regulations 1976<sup>(a)</sup> (which provides for the issue of a certificate in the form of a special statement by a doctor on the basis of a written report made by another doctor).

### **Finance**

**22.**-(1) Subject to paragraph (2), the contract must contain a term which has the effect of requiring the Local Health Board to make payments to the contractor under the contract promptly and in accordance with both the terms of the contract and any other conditions relating to the payment contained in directions given by the Assembly under section 28T of the Act. (GMS contracts : payments).

(2) The obligation referred to in paragraph (1) is subject to any right the Local Health Board may have to set off against any amount payable to the contractor under the contract any amount-

- (a) that is owed by the contractor to the Local Health Board under the contract; or
- (b) that the Local Health Board may withhold from the contractor in accordance with the terms of the contract or any applicable provisions contained in directions given by the Assembly under section 28T of the Act.

**23.** The contract must contain a term to the effect that where, pursuant to directions under section 16BB(4) Assembly's directions: exercise of functions)(**b**) or 28T (GMS Contracts: payments) payments) of the Act, a Local Health Board is required to make a payment to a contractor under a contract but subject to conditions, those conditions are to be a term of the contract.

### **Fees and charges**

**24.**-(1) The contract must contain terms relating to fees and charges which have the same effect as those set out in paragraphs (2) to (4).

(2) The contractor shall not, directly or indirectly, demand or accept a fee or other remuneration from any patient of its for -

- (a) the provision of any treatment whether under the contract or otherwise; or
- (b) any prescription or repeatable prescription for any drug, medicine or appliance,

except in the circumstances set out in Schedule 5.

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(a) S.I. 1976/615. Regulation 2 was amended by S.I. 1982/699, 1992/647, 1994/2975, 1995/987 and 2000/950.

(b)

(3) Where a person applies to a contractor for the provision of essential services and claims to be on that contractor's list of patients, but fails to produce his or her medical card on request and the contractor has reasonable doubts about that person's claim, the contractor shall give any necessary treatment and shall be entitled to demand and accept a reasonable fee in accordance with paragraph (e) of Schedule 5, subject to the provision for repayment contained in paragraph (4).

(4) Where a person from whom a contractor received a fee under paragraph (e) of Schedule 5 applies to the Local Health Board for a refund within 14 days of payment of the fee (or such longer period not exceeding a month as the Local Health Board may allow if it is satisfied that the failure to apply within 14 days was reasonable) and the Local Health Board is satisfied that the person was on the contractor's list of patients when the treatment was given, the Local Health Board may recover the amount of the fee from the contractor, by deduction from its remuneration or otherwise, and shall pay that amount to the person who paid the fee.

### **Arrangements on termination**

25. A contract shall make suitable provision for arrangements on termination of a contract, including the consequences (whether financial or otherwise) of the contract ending.

### **Other contractual terms**

26.-(1) A contract must, unless it is of a type or nature to which a particular provision does not apply, contain other terms which have, the same effect as those specified in Schedule 6 except paragraphs 31(6) to (8), 35(5) to (9), 36(5) to (17), 99(5) to (14) and 100.

(2) The paragraphs specified in paragraph (1) shall have effect in relation to the matters set out in those paragraphs.

## **PART 6**

### **FUNCTIONS OF LOCAL MEDICAL COMMITTEES**

27.-(1) The functions of a Local Medical Committee which are prescribed for the purposes of section 45A(9) (Local Medical Committees) of the Act(a) are -

- (a) the consideration of any complaint made to it by any medical practitioner against a medical practitioner specified in paragraph (2) providing services under a contract in the relevant area involving any question of the efficiency of those services;
- (b) the reporting of the outcome of the consideration of any such complaint to the Local Health Board with whom the contract is held in cases where that consideration gives rise to any concerns relating to the efficiency of services provided under a contract;
- (c) the making of arrangements for the medical examination of a medical practitioner specified in paragraph (2), where the contractor or the Local Health Board is concerned that the medical practitioner is incapable of adequately providing services under the contract and it so requests with the agreement of the medical practitioner concerned; and
- (d) the consideration of the report of any medical examination arranged in accordance with sub-paragraph (c) and the making of a written report as to the capability of the medical practitioner of adequately providing services under the contract to the medical practitioner concerned, the contractor and the Local Health Board with whom the contractor holds a contract.

(2) The medical practitioner referred to in paragraph (1)(c) is a medical practitioner who is -

- (a) a contractor;
- (b) one of two or more individuals practising in partnership who hold a contract; or
- (c) a legal and beneficial shareholder in a company which holds a contract.

(3) In this regulation, "the relevant area" means the area for which the Local Medical Committee is formed.

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(a) Section 45A was inserted into the Act by paragraph 23 of Schedule 11 to the 2003 Act.

## PART 7

### TRANSITIONAL PROVISIONS

#### Commencement

28. The contract shall provide for services to be provided under it from any date after 31st March 2004.

#### Additional services

29.-(1) Where the contract is with one of the persons specified in paragraph (2), the contract must subject to regulation 17 provide for the contractor to provide in core hours to the contractor's registered patients and persons accepted by it as temporary residents, such of the additional services as are equivalent to services which that medical practitioner or practitioners was or were providing to his, her or their patients on the date that the contract is entered into except to the extent that -

- (a) the provision of any of those services by that medical practitioner or practitioners was due to come to an end on or before the date in which services are required to start being provided under the contract; or
- (b) prior to the signing of the contract, the Local Health Board has accepted a written request from the contractor that the contract should not require it to provide all or any of those additional services.

(2) The persons referred to in paragraph (1) are -

- (a) an individual medical practitioner who, on 31st March 2004, was providing services under section 29 of the Act (general medical services);
- (b) two or more individuals practising in partnership at least one of whom was, on 31st March 2004, a medical practitioner providing services under that section; or
- (c) a company in which one or more of the shareholders was, on 31st March 2004, a medical practitioner providing services under that section.

(3) This regulation applies only to contracts under which services are to be provided from 1st April 2004.

#### Out of hours services

30.-(1) Subject to paragraph 10 of Schedule 6, a contract under which services are to be provided before 1st January 2005 (whether or not such services will be provided after that date) must provide for the services specified in paragraph (2) to be provided throughout the out of hours period unless -

- (a) the Local Health Board has accepted in writing, prior to the signing of the contract, a written request from the contractor that the contract should not require the contractor to make such provision;
- (b) the contract is, at the date on which it is signed, with -
  - (i) a medical practitioner who on 31st March 2004, is or was relieved of responsibility for providing services to his or her patients under paragraph 18(2) of Schedule 2 to the National Health Service (General Medical Services) Regulations 1992(a),
  - (ii) a partnership in which all of the partners who are general medical practitioners are, or were on 31st March 2004, relieved of responsibility for providing services to their patients under that paragraph or
  - (iii) a company in which all of the general medical practitioners who own shares in that company are, or were on 31st March 2004, relieved of responsibility for providing services to their patients under that paragraph ;
- (c) the contractor has opted out in accordance with paragraph 4 or 5 of Schedule 3; or
- (d) the contract has been otherwise varied to exclude a requirement to make such provision.

(2) The services referred to in paragraph (1) are -

- (a) the services which must be provided in core hours under regulation 15; and
- (b) such additional services as are included in the contract pursuant to regulation 29.

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(a) S.I. 1992/635. Paragraph 18 was amended by S.I. 1996/702; 2002/1896.

**31.**-(1) Where the contract is with -

- (a) an individual medical practitioner who is, or was on 31st March 2004, responsible for providing services during all or part of the out of hours period to the patients of a medical practitioner who meets the requirements in paragraph (2);
- (b) two or more individuals practising in partnership at least one of whom is or was or on 31st March 2004, a medical practitioner responsible for providing such services; or
- (c) a company in which one or more of the shareholders is or was on 31st March 2004, a medical practitioner responsible for providing such services,

the contract with that contractor must require the contractor to continue to provide such services to the patients of the exempt contractor until the happening of one of the events in paragraph (3).

(2) The requirements referred to in paragraph (1)(a) are that -

- (a) the medical practitioner was relieved of responsibility for providing services to his or her patients under paragraph 18(2) of Schedule 2 to the National Health Service (General Medical Services) Regulations 1992(a); and
- (b) he or she -
  - (i) has entered or intends to enter into a contract which does not include out of hours services pursuant to regulation 30(1)(b)(i),
  - (ii) is one of two or more individuals practising in partnership who have entered or intends to enter will into a contract which does not include out of hours services pursuant to regulation 30(1)(b)(ii), or
  - (iii) is the owner of shares in a company which has entered or intends to enter into a contract which does not include out of hours services pursuant to regulation 30(1)(b) (iii).

(3) The events referred to in paragraph (1) are -

- (a) the contractor has opted out of the provision of out of hours services in accordance with paragraph 4 or 5 of Schedule 3; or
- (b) the Local Health Board (and, if it is different, the Local Health Board with whom the exempt contractor holds its contract) has or have agreed in writing that the contractor need no longer provide some or all of those services to some or all of those patients;

(4) In this regulation "exempt contractor" means a contractor who is exempt from providing out of hours services pursuant to regulation 30(1)(b).

32. A contract which includes the provision of out of hours services pursuant to regulation 30 or 31 must contain terms which have the same effect as those set out in Schedule 7.

26th February 2004

D.Elis-Thomas

Signed on behalf of the National Assembly for Wales under section 66(1) of the Government of Wales Act 1998(b)

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(a) S.I. 1996/702; 2002/1896.

(b) 1998 c.38.

SCHEDULE 1

Regulation 2

**REPEAT DISPENSING FORMS**

**PART 1**

**REPEATABLE PRESCRIPTION**

Pharmacy Stamp	Age  DoB	Title, Forename, Surname & Address	
Number of days treatment NB. Ensure dose is stated			
	GP REPEAT DISPENSING <b>Authorising no. of issues = [example] 12</b>		OFFICE USE  RA
<i>[TO BE SIGNED BY GP]</i>		<i>[DATE]</i>	
<input type="checkbox"/>  <input checked="" type="checkbox"/>	<i>[prescriber's and contractor's name address and telephone no.]</i>  LHB NAME                  CODE		RA

**PART 2**

**BATCH ISSUE**

Pharmacy Stamp	Age  DoB	Title, Forename, Surname & Address	
Number of days treatment NB. Ensure dose is stated			
	GP REPEAT DISPENSING		OFFICE USE  RA
Repeat dispensing: [example] 6 of 12		<i>[print the date repeats authorised]</i>	[example] 6
<input type="checkbox"/>  <input checked="" type="checkbox"/>	<i>[prescriber's and contractor's name , address and telephone no.]</i>  LHB NAME                      CODE		RA



## SCHEDULE 2

Regulation 16

### ADDITIONAL SERVICES

#### Additional services generally

1. The contractor shall provide, in relation to each additional service, such facilities and equipment as are necessary to enable it properly to perform that service.

#### Cervical screening

2.-(1) A contractor whose contract includes the provision of cervical screening services shall -

- (a) provide all the services described in sub- paragraph (2); and
- (b) make such records as are referred to in sub-paragraph (3).

(2) The services referred to in sub-paragraph (1)(a) are -

- (a) the provision of any necessary information and advice to assist women identified by the Local Health Board as recommended nationally for a cervical screening test in making an informed decision as to participation in the NHS Cervical Screening Programme;
- (b) the performance of cervical screening tests on women who have agreed to participate in that Programme;
- (c) arranging for women to be informed of the results of the test; and
- (d) ensuring that test results are followed up appropriately.

(3) The records referred to in sub-paragraph (1)(b) are an accurate record of the carrying out of a cervical screening test, the result of the test and any clinical follow up requirements.

#### Contraceptive services

3.-(1) A contractor whose contract includes the provision of contraceptive services shall make available to all its patients who request such services the services described in sub-paragraph (2).

(2) The services referred to in sub-paragraph (1) are -

- (a) the giving of advice about the full range of contraceptive methods;
- (b) where appropriate, the medical examination of patients seeking such advice;
- (c) the treatment of such patients for contraceptive purposes and the prescribing of contraceptive substances and appliances (excluding the fitting and implanting of intrauterine devices and implants);
- (d) the giving of advice about emergency contraception and where appropriate, the supplying or prescribing of emergency hormonal contraception or, where the contractor has a conscientious objection to emergency contraception, prompt referral to another provider of primary medical services who does not have such conscientious objections;
- (e) the provision of advice and referral in cases of unplanned or unwanted pregnancy, including advice about the availability of free pregnancy testing in the practice area and, where appropriate, where the contractor has a conscientious objection to the termination of pregnancy, prompt referral to another provider of primary medical services who does not have such conscientious objections;
- (f) the giving of initial advice about sexual health promotion and sexually transmitted infections; and
- (g) the referral as necessary for specialist sexual health services, including tests for sexually transmitted infections.

## **Vaccinations and immunisations**

4.-(1) A contractor whose contract includes the provision of vaccinations and immunisations shall comply with the requirements in sub-paragraphs (2) and (3).

(2) The contractor shall -

- (a) offer to provide to patients all vaccinations and immunisations (excluding childhood vaccinations and immunisations) of a type and in the circumstances for which a fee was provided for under the 2003-04 Statement of Fees and Allowances made under regulation 34 of the National Health Service (General Medical Services) Regulations 1992<sup>(a)</sup> other than influenza vaccination;
- (b) provide appropriate information and advice to patients about such vaccinations and immunisations;
- (c) record in the patient's record kept in accordance with paragraph 72 of Schedule 6 any refusal of the offer referred to in paragraph (a);
- (d) where the offer is accepted, administer the vaccinations and immunisations and include in the patient's record kept in accordance with paragraph 72 of Schedule 6 -
  - (i) the patient's consent to the vaccination or immunisation or the name of the person who gave consent to the vaccination or immunisation and his relationship to the patient,
  - (ii) the batch numbers, expiry date and title of the vaccine,
  - (iii) the date of administration,
  - (iv) in a case where two vaccines are administered in close succession, the route of administration and the injection site of each vaccine,
  - (v) any contra-indications to the vaccination or immunisation, and
  - (vi) any adverse reactions to the vaccination or immunisation.

(3) The contractor shall ensure that all staff involved in administering vaccines are trained in the recognition and initial treatment of anaphylaxis.

## **Childhood vaccinations and immunisations**

5.-(1) A contractor whose contract includes the provision of childhood vaccinations and immunisations shall comply with the requirements in sub-paragraphs (2) and (3).

(2) The contractor shall -

- (a) offer to provide to children all vaccinations and immunisations of a type and in the circumstances for which a fee was provided for under the 2003-04 Statement of Fees and Allowances made under regulation 34 of the National Health Service (General Medical Services) Regulations 1992;
- (b) provide appropriate information and advice to patients and, where appropriate, their parents, about such vaccinations and immunisations;
- (c) record in the patient's record kept in accordance with paragraph 72 of Schedule 6 any refusal of the offer referred to in paragraph (a);
- (d) where the offer is accepted, administer the vaccinations and immunisations and include in the patient's record kept in accordance with paragraph 72 of Schedule 6 -
  - (i) the name of the person who gave consent to the vaccination or immunisation and that person's relationship to the patient;
  - (ii) the batch numbers, expiry date and title of the vaccine;
  - (iii) the date of administration;
  - (iv) in a case where two vaccines are administered in close succession, the route of administration and the injection site of each vaccine;
  - (v) any contra-indications to the vaccination or immunisation; and
  - (vi) any adverse reactions to the vaccination or immunisation.

(3) The contractor shall ensure that all staff involved in administering vaccines are trained in the recognition and initial treatment of anaphylaxis.

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(a) S.I. 1992/635; regulation 34 was amended by S.I. 1993/540, 1997/2468; and 2002/1896 (W. 197).

## **Child health surveillance**

6.-(1) A contractor whose contract includes the provision of child health surveillance services shall, in respect of any child under the age of five for whom it has responsibility under the contract -

- (a) provide all the services described in sub-paragraph (2), other than any examination so described which the parent refuses to allow the child to undergo, until the date upon which the child attains the age of five years; and
- (b) maintain such records as are specified in sub-paragraph(3).

(2) The services referred to in sub-paragraph (1)(a) are -

- (a) the monitoring -
  - (i) by the consideration of any information concerning the child received by or on behalf of the contractor, and
  - (ii) on any occasion when the child is examined or observed by or on behalf of the contractor (whether pursuant to paragraph (b) or otherwise),

of the health, well-being and physical, mental and social development (all of which characteristics are referred to in this paragraph as "development") of the child while under the age of 5 years with a view to detecting any deviations from normal development;

- (b) the examination of the child at a frequency that has been agreed with the Local Health Board in accordance with the nationally agreed evidence based programme set out in the fourth edition of "Health for all Children"**(a)**.

(3) The records mentioned in sub-paragraph (1)(b) are an accurate record of -

- (a) the development of the child while under the age of 5 years, compiled as soon as is reasonably practicable following the first examination of that child and, where appropriate, amended following each subsequent examination; and
- (b) the responses (if any) to offers made to the child's parent for the child to undergo any examination referred to in sub- paragraph (2)(b).

## **Maternity medical services**

7.-(1) A contractor whose contract includes the provision of maternity medical services shall -

- (a) provide to female patients who have been diagnosed as pregnant all necessary maternity medical services throughout the antenatal period;
- (b) provide to female patients and their babies all necessary maternity medical services throughout the postnatal period other than neonatal checks;
- (c) provide all necessary maternity medical services to female patients whose pregnancy has terminated as a result of miscarriage or abortion or, where the contractor has a conscientious objection to the termination of pregnancy, prompt referral to another provider of primary medical services who does not have such conscientious objections.

(2) In this paragraph -

"antenatal period" means the period from the start of the pregnancy to the onset of labour;

"maternity medical services" means ;

- (a) in relation to female patients (other than babies) all primary medical services relating to pregnancy, excluding intra partum care; and
- (b) in relation to babies, any primary medical services necessary to their first 14 days of life;

"postnatal period" means the period starting from the conclusion of delivery of the baby or the patient's discharge from secondary care services, whichever is the later, and ending on the fourteenth day after the birth.

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(a) Hall and Elliman, January 2003, Oxford University Provisions ISBN 0-19-85188..

## **Minor surgery**

8.-(1) A contractor whose contract includes the provision of minor surgery shall comply with the requirements in sub-paragraphs (2) and (3).

(2) The contractor shall make available to patients where appropriate -

- (a) curettage;
- (b) cautery; and
- (c) cryocautery of warts, verrucae and other skin lesions.

(3) The contractor shall ensure that its record of any treatment provided under this paragraph includes the consent of the patient to that treatment.

## **SCHEDULE 3**

Regulation 17

### **OPT OUTS OF ADDITIONAL AND OUT OF HOURS SERVICES**

#### **Opt outs of additional services: general**

1.-(1) In this Schedule -

"opt out notice" means a notice given under sub-paragraph (5) to permanently opt out or temporarily opt out of the provision of the additional service;

"permanent opt out" in relation to the provision of an additional service that is funded through the global sum, means the termination of the obligation under the contract for the contractor to provide that service; and "permanently opt out" shall be construed accordingly;

"permanent opt out notice" means an opt out notice to permanently opt out;

"preliminary opt out notice" means a notice given under sub-paragraph (2) that a contractor wishes to temporarily opt out or permanently opt out of the provision of an additional service;

"temporary opt out" in relation to the provision of an additional service that is funded through the global sum, means the suspension of the obligation under the contract for the contractor to provide that service for a period of more than six months and less than twelve months and includes an extension of a temporary opt out and "temporarily opt out" and "temporarily opted out" shall be construed accordingly; and

"temporary opt out notice" means an opt out notice to temporarily opt out.

(2) A contractor who wishes to permanently or temporarily opt out shall give to the relevant Local Health Board in writing a preliminary opt out notice which shall state the reasons for wishing to opt out.

(3) As soon as is reasonably practicable and in any event within the period of 7 days beginning with the receipt of the preliminary opt out notice by the Local Health Board, the Local Health Board shall enter into discussions with the contractor concerning the support which the Local Health Board may give the contractor, or concerning other changes which the Local Health Board or the contractor may make, which would enable the contractor to continue to provide the additional service and the Local Health Board and the contractor shall use reasonable endeavours to achieve this aim.

(4) The discussions mentioned in sub-paragraph (3) shall be completed within the period of 10 days beginning with the date of the receipt of the preliminary opt out notice by the Local Health Board or as soon as reasonably practicable thereafter.

(5) Subject to sub-paragraph (9), if following the discussions mentioned in sub-paragraph (3), the contractor still wishes to opt out of the provision of the additional service, it shall send an opt out notice to the relevant Local Health Board.

(6) An opt out notice shall specify -

- (a) the additional service concerned;

- (b) whether the contractor wishes to -
  - (i) permanently opt out; or
  - (ii) temporarily opt out;
- (c) the reasons for wishing to opt out;
- (d) the date from which the contractor would like the opt out to commence, which must -
  - (i) in the case of a temporary opt out be at least 14 days after the date of service of the opt out notice, and
  - (ii) in the case of a permanent opt out must be the day either three or six months after the date of service of the opt out notice, and
- (e) in the case of a temporary opt out, the desired duration of the opt out.

(7) Where a contractor has given two previous temporary opt out notices within the period of three years ending with the date of the service of the latest opt out notice (whether or not the same additional service is concerned), the latest opt out notice shall be treated as a permanent opt out notice (even if the opt out notice says that it wishes to temporarily opt out).

(8) Paragraph 2 applies following the giving of a temporary opt out notice and paragraph 3 applies following the giving of a permanent opt out notice or a temporary opt out notice which pursuant to sub-paragraph (7) is treated as a permanent opt out notice.

(9) No temporary opt out notice may be served by a contractor prior to 1st April 2004.

### **Temporary opt outs and permanent opt outs following temporary opt outs**

2.-(1) As soon as is reasonably practicable and in any event within the period of 7 days beginning with the date of receipt of a temporary opt out notice under paragraph 1(5), the Local Health Board shall -

- (a) approve the opt out notice and specify in accordance with sub-paragraphs (3) and (4) the date on which the temporary opt out is to commence and the date that it is to come to an end ("the end date"); or
- (b) reject the opt out notice in accordance with sub-paragraph (2),

and shall notify the contractor of its decision as soon as possible, including reasons for its decision.

(2) A Local Health Board may reject the opt out notice on the ground that the contractor-

- (a) is providing additional services to patients other than its own registered patients or enhanced services; or
- (b) has no reasonable need temporarily to opt out having regard to its ability to deliver the additional service.

(3) The date specified by the Local Health Board for the commencement of the temporary opt out shall wherever reasonably practicable be the date requested by the contractor in its opt out notice.

(4) Before determining the end date, the Local Health Board shall make reasonable efforts to reach agreement with the contractor.

(5) Where the Local Health Board approves an opt out notice, the contractor's obligation to provide the additional service specified in the notice shall be suspended from the date specified by the Local Health Board in its decision under sub-paragraph (1), and shall remain suspended until the end date unless -

- (a) the contractor and the Local Health Board agree in writing an earlier date, in which case the suspension shall come to an end on the earlier date agreed;
- (b) the Local Health Board specifies a later date under sub-paragraph (6), in which case the suspension shall end on the later date specified;
- (c) sub-paragraph (7) applies and the contractor refers the matter to the NHS dispute resolution procedure or the court, in which case the suspension shall end -
  - (i) where the outcome of the dispute is to uphold the decision of the Local Health Board, on the day after the date of the decision of the Assembly or the court,
  - (ii) where the outcome of the dispute is to overturn the decision of the Local Health Board, 28 days after the decision of the Assembly or the court, or
  - (iii) where the contractor ceases to pursue the NHS dispute resolution procedure or court proceedings, on the day after the date that the contractor withdraws its claim or the procedure is or proceedings are otherwise terminated by the Assembly or the court;

(d) sub-paragraph (9) applies and -

- (i) the Local Health Board refuses the contractor's request for a permanent opt out within the period of 28 days ending with the end date, in which case the suspension shall come to an end 28 days after the end date;
- (ii) the Local Health Board refuses the contractor's request for a permanent opt out after the end date, in which case the suspension shall come to an end 28 days after the date of service of the notice; or
- (iii) the Local Health Board notifies the contractor after the end date that the Assembly has not approved its proposed decision to refuse the contractor's request to permanently opt out under sub-paragraph (14), in which case the suspension shall come to an end 28 days after the date of service of the notice under this paragraph.

(6) Before the end date, a Local Health Board may, in exceptional circumstances and with the agreement of the contractor, notify the contractor in writing of a later date on which the temporary opt out is to come to an end, being a date no more than six months later than the end date.

(7) Where the Local Health Board considers that -

- (a) the contractor will be unable to satisfactorily provide the additional service at the end of the temporary opt out; and
- (b) it would not be appropriate to exercise its discretion under sub-paragraph (6) to specify a later date on which the temporary opt out is to come to an end or the contractor does not agree to a later date,

the Local Health Board may notify the contractor in writing at least 28 days before the end date that a permanent opt out shall follow a temporary opt out.

(8) Where a Local Health Board notifies the contractor under sub-paragraph (7) that a permanent opt out shall follow a temporary opt out, the permanent opt out shall take effect immediately after the end of the temporary opt out.

(9) A contractor who has temporarily opted out may, at least three months prior to the end date, notify the relevant Local Health Board in writing that it wishes to permanently opt out of the additional service in question.

(10) Where the contractor has notified the Local Health Board under sub-paragraph (9) that it wishes to permanently opt out, the temporary opt out shall be followed by a permanent opt out beginning on the day after the end date unless the Local Health Board refuses the contractor's request to permanently opt out by giving a notice in writing to the contractor to this effect.

(11) A Local Health Board may only give a notice under sub-paragraph (10) with the approval of the Assembly.

(12) Where a Local Health Board seeks the approval of the Assembly to a proposed decision to refuse a permanent opt out, it shall notify the contractor of having done so.

(13) If the Assembly has not reached a decision as to whether or not to approve the Local Health Board's proposed decision to refuse a permanent opt out before the end date, the contractor's obligation to provide the additional service shall remain suspended until the date specified in sub-paragraph (5)(d)(ii) or (iii) (whichever is applicable).

(14) Where after the end date the Assembly notifies the Local Health Board that it does not approve the Local Health Board's proposed decision to refuse a permanent opt out, the Local Health Board shall notify the contractor in writing of this fact as soon as is reasonably practicable.

(15) A temporary opt out or permanent opt out commences, and a temporary opt out ends, at 08.00 on the relevant day unless -

- (a) the day is a Saturday, Sunday, Good Friday, Christmas Day, or a bank holiday, in which case the opt out shall take effect on the next working day at 08.00; or
- (b) the Local Health Board and the contractor agree a different day or time.

### **Permanent opt outs**

3.-(1) In this paragraph -

"A day" is the day specified by the contractor in its permanent opt out notice to a Local Health Board for the commencement of the permanent opt out;

"B day" is the day six months after the date of service of the permanent opt out notice; and

"C day" is the day nine months after the date of service of the permanent opt out notice.

(2) As soon as is reasonably practicable and in any event within the period of 28 days beginning with the date of receipt of a permanent opt out notice under paragraph 1(5) (or temporary opt out notice which is treated as a permanent opt out notice under paragraph 1(7)), the Local Health Board shall -

- (a) approve the opt out notice; or
- (b) reject the opt out notice in accordance with sub-paragraph (3),

and shall notify the contractor of its decision as soon as possible, including reasons for its decision where its decision is to reject the opt out notice.

(3) A Local Health Board may reject the opt out notice on the ground that the contractor is providing an additional service to patients other than its registered patients or enhanced services.

(4) A contractor may not withdraw an opt out notice once it has been approved by the Local Health Board in accordance with sub-paragraph (2)(a) without the Local Health Board's agreement.

(5) If the Local Health Board approves the opt out notice under sub-paragraph (2)(a), it shall use its reasonable endeavours to make arrangements for the contractor's registered patients to receive the additional service from an alternative provider from A day.

(6) The contractor's duty to provide the additional service shall terminate on A day unless the Local Health Board serves a notice under sub-paragraph (7) (extending A day to B day or C day).

(7) If the Local Health Board is not successful in finding an alternative provider to take on the provision of the additional service from A day, then it shall notify the contractor in writing of this fact no later than one month before A day, and -

- (a) in a case where A day is three months after service of the opt out notice, the contractor shall continue to provide the additional service until B day unless at least one month before B day it receives a notice in writing from the Local Health Board under sub-paragraph (8) that despite using its reasonable endeavours, it has failed to find an alternative provider to take on the provision of the additional service from B day;
- (b) in a case where A day is six months after the service of the opt out notice, the contractor shall continue to provide the additional service until C day unless at least one month before C day it receives a notice from the Local Health Board under sub-paragraph (11) that it has made an application to the Assembly under sub-paragraph (10) seeking its approval of a decision to refuse a permanent opt out or to delay the commencement of a permanent opt out until after C day.

(8) Where in accordance with sub-paragraph (7)(a) the permanent opt out is to commence on B day and the Local Health Board, despite using its reasonable endeavours has failed to find an alternative provider to take on the provision of the additional service from that day, it shall notify the contractor in writing of this fact at least one month before B day, in which case the contractor shall continue to provide the additional service until C Day unless at least one month before C day it receives a notice from the Local Health Board under sub-paragraph (11) that it has applied to the Assembly under sub-paragraph (10) seeking the approval of the Assembly to a decision to refuse a permanent opt out or to postpone the commencement of a permanent opt out until after C day.

(9) As soon as is reasonably practicable and in any event within 7 days of the Local Health Board serving a notice under sub-paragraph (8), the Local Health Board shall enter into discussions with the contractor concerning the support that the Local Health Board may give to the contractor or other changes which the Local Health Board or the contractor may make in relation to the provision of the additional service until C day.

(10) The Local Health Board may, if it considers that there are exceptional circumstances, make an application to the Assembly for approval of a decision to -

- (a) refuse a permanent opt out; or
- (b) postpone the commencement of a permanent opt out until after C day.

(11) As soon as practicable after making an application under sub-paragraph (10) to the Assembly, the Local Health Board shall notify the contractor in writing that it has made such an application.

(12) On receiving an application under sub-paragraph (10) for approval of a decision to refuse a permanent opt out, the Assembly shall -

- (a) approve the Local Health Board's application;
- (b) reject the Local Health Board's application, but nonetheless recommend a different date for the

commencement of the permanent opt out which shall be later than C day; or

(c) reject the Local Health Board's application.

(13) On receiving an application under sub-paragraph (10) for approval of a decision to postpone the commencement of a permanent opt out until after C day, the Assembly shall -

(a) approve the Local Health Board's application;

(b) reject the Local Health Board's application, but nonetheless recommend-

(i) that the permanent opt out commence on an earlier date to that proposed by the Local Health Board in its application, or

(ii) that the permanent opt out be refused; or

(c) reject the Local Health Board's application.

(14) The Assembly shall notify the Local Health Board and the contractor in writing of its decision under sub-paragraph (12) or (13) as soon as is practicable, including reasons for its decision.

(15) Where the Assembly -

(a) approves a decision to refuse an opt out under sub-paragraph (12)(a); or

(b) recommends that a permanent opt out be refused under sub-paragraph (13)(b)(ii),

the Local Health Board shall notify the contractor in writing that it may not opt out of the additional service.

(16) Where a Local Health Board notifies a contractor under sub-paragraph (15), the contractor may not serve a preliminary opt out notice in respect of that additional service for a period of 12 months beginning with the date of service of the Local Health Board's notice under sub-paragraph (15) unless there has been a change in the circumstances of the contractor which affects its ability to deliver services under the contract.

(17) Where the Assembly -

(a) recommends a different date for the commencement of the permanent opt out under sub-paragraph (12)(b);

(b) approves a Local Health Board's application to postpone a permanent opt out under sub-paragraph (13)(a); or

(c) recommends an earlier date to that proposed by the Local Health Board in its application under sub-paragraph (13)(b)(i),

the Local Health Board shall in accordance with the decision of the Assembly notify the contractor in writing of its decision and the notice shall specify the date from which the permanent opt out shall commence.

(18) Where the Assembly rejects the Local Health Board's application under sub-paragraph (12)(c) or (13)(c), the Local Health Board shall notify the contractor in writing that there shall be a permanent opt out and the permanent opt out shall commence on C day or 28 days after the date of service of the Local Health Board's notice, whichever is the later.

(19) If the Assembly has not reached a decision on the Local Health Board's application under sub-paragraph (10) before C day, the contractor's obligation to provide the additional service shall continue until a notice is served on it by the Local Health Board under sub-paragraph (17) or (18).

(20) Nothing in sub-paragraphs (1) to (19) above shall prevent the contractor and the Local Health Board from agreeing a different date for the termination of the contractor's duty under the contract to provide the additional service and accordingly, varying the contract in accordance with paragraph 102(1) of Schedule 6.

(21) The permanent opt out takes effect at 08.00 on the relevant day unless -

(a) the day is a Saturday, Sunday, Good Friday, Christmas Day, or a bank holiday, in which case the opt out shall take effect on the next working day at 08.00; or

(b) the Local Health Board and the contractor agree a different day or time.

#### **Out of hour opt outs where the opt out notice is served after 30th September 2004**

4.-(1) This paragraph applies where a contractor wishes to serve or serves an out of hours opt out notice after 30th September 2004.

(2) A contractor which wishes to terminate its obligation to provide out of hours services which was included in the contract pursuant to regulation 30 shall notify the relevant Local Health Board in writing to that effect ("an out



of hours opt out notice").

(3) An out of hours opt out notice shall specify the date from which the contractor would like the opt out to take effect, which must be either three or six months after the date of service of the out of hours opt out notice.

(4) As soon as is reasonably practicable and in any event within 28 days of receiving the out of hours opt out notice, the Local Health Board shall approve the notice and specify in accordance with sub-paragraph (6) the date on which the out of hours opt out is to commence ("OOH day").

(5) The Local Health Board shall notify the contractor of its decision as soon as possible.

(6) The date specified in sub-paragraph (4) shall be the date specified in the out of hours opt out notice.

(7) A contractor may not withdraw an out of hours opt out notice once it has been approved by the Local Health Board under sub-paragraph (4) without the Local Health Board's agreement.

(8) Following receipt of the out of hours opt out notice, the Local Health Board must use its reasonable endeavours to make arrangements for the contractor's registered patients to receive the out of hours services from an alternative provider from OOH day.

(9) Sub-paragraphs (6) to (21) of paragraph 3 shall apply to an out of hours opt out as they apply to a permanent opt out and as if the reference to "A day" was a reference to "OOH day" and the reference in paragraph 3(16) to a "preliminary opt out notice" was a reference to "an out of hours opt out notice".

#### **Out of hours opt out where the opt out notice is served before 1st October 2004**

5.-(1) This paragraph shall apply where a contractor wishes to serve or serves an out of hours opt out notice before 1st October 2004.

(2) In this paragraph -

"OOH day" is the day specified by the Local Health Board for the commencement of the out of hours opt out in its decision under sub-paragraph (5);

"OOHB day" is the day six months after the date of service of the out of hours opt out notice; and

"OOHC day" is the day specified by the Local Health Board in its decision under sub-paragraph (11) or (13) (which must be nine months after the date of service of the out of hours opt out notice or before 2nd January 2005).

(3) A contractor which wishes to terminate its obligation to provide out of hours services which was included in the contract pursuant to regulation 30 shall notify the relevant Local Health Board in writing to that effect ("an out of hours opt out notice").

(4) An out of hours opt out notice shall state the date on which the contractor would like the opt out to take effect, which must either be three or six months after the date of service of the out of hours opt out notice.

(5) As soon as is reasonably practicable and in any event within 28 days of receiving the out of hours opt out notice, the Local Health Board shall approve the notice and specify in accordance with sub-paragraphs (6) and (7) the date on which the out of hours opt out is to commence ("OOH day") and the Local Health Board shall notify the contractor in writing of its decision as soon as possible, including reasons for its decision.

(6) Subject to sub-paragraph (7), OOH day shall be -

(a) the date specified in the out of hours opt out notice; or

(b) any other date before 2nd January 2005.

(7) A Local Health Board may not specify under sub-paragraph (5) a date earlier than the date specified in the out of hours opt out notice.

(8) A contractor may not withdraw an out of hours opt out notice once it has been approved by a Local Health Board under sub-paragraph (5) without the Local Health Board's agreement.

(9) Following receipt of the out of hours opt out notice, the Local Health Board must use its reasonable endeavours to make arrangements for the contractor's registered patients to receive out of hours services from an alternative provider from OOH day.

(10) The contractor's duty to provide the out of hours services shall terminate on OOH day unless the Local

Health Board -

- (a) serves a notice under sub-paragraph (11) (extending OOH day to OOHB day or OOHC day); or
- (b) makes an application under sub-paragraph (14) (seeking the approval of the Assembly to a decision to refuse an opt out or to delay the taking of effect of an opt out until after OOH day.

(11) If the Local Health Board is not successful in finding an alternative provider to take on the provision of the out hours services from OOH day, then it shall notify the contractor in writing of this fact no later than one month before OOH day, and -

- (a) in a case where OOH day is three months after service of the out of hours opt out notice, the contractor shall continue to provide the out of hours services until OOHB day unless at least one month before OOHB day it receives a notice in writing from the Local Health Board under sub-paragraph (13) that despite using its reasonable endeavours, it has failed to find an alternative provider to take on the provision of the out of hours services from OOHB day;
- (b) in a case where OOH day is after the day three months after the service of the out of hours opt out notice, the contractor shall continue to provide the out of hours services until OOHC day (which shall be specified by the Local Health Board in accordance with sub-paragraph (12) and included in its notice to the contractor under this sub-paragraph) unless at least one month before OOHC day it receives a notice from the Local Health Board under sub-paragraph (16) that it has made an application to the Assembly under sub-paragraph (14) seeking its approval to a decision to refuse an opt out or to delay the commencement of the opt out until after OOHC day.

(12) OOHC day shall be any day before 2nd January 2005 or the day nine months after the service of the out of hours opt out notice.

(13) Where in accordance with sub-paragraph (11)(a) the out of hours opt out is to commence on OOHB day and the Local Health Board, despite using its reasonable endeavours has failed to find an alternative provider to take on the provision of the out of hours services from that day, it shall notify the contractor in writing of this fact at least one month before OOHB day, in which case the contractor shall continue to provide the out of hours services until OOHC day (which shall be specified by the Local Health Board in accordance with sub-paragraph (12) and included in its notice to the contractor under this sub-paragraph) unless at least one month before OOHC day it receives a notice from the Local Health Board under sub-paragraph (16) that it has applied to the Assembly under sub-paragraph (14) seeking the approval of the Assembly to a decision to refuse an opt out or to postpone the commencement of an opt out until after OOHC day.

(14) The Local Health Board may, if it considers there are exceptional circumstances, make an application to the Assembly for approval of a decision to -

- (a) refuse an opt out; or
- (b) postpone the commencement of an opt out until after -
  - (i) OOHC day, or
  - (ii) OOH day where OOH day is 1st January 2005 and 1st January 2005 is nine months or more after the date of the out of hours opt out notice.

(15) Where OOH day is 1st January 2005 and 1st January 2005 is nine months or more after the date of the out of hours opt out notice, an application under sub-paragraph (14) shall be made at least one month before OOH day.

(16) As soon as practicable after making an application under sub-paragraph (14) to the Assembly, the Local Health Board shall notify the contractor in writing that it has made such an application.

(17) Sub-paragraphs (12) to (21) of paragraph 3 shall apply to an out of hours opt out as they apply to a permanent opt out and as if the reference to "C day" was a reference to OOHC day or OOH day where OOH day is 1st January 2005 and 1st January 2005 is nine months or more after the date of the out of hours opt out notice.

### **Informing patients of opt outs**

6.-(1) Prior to any opt out taking effect, the Local Health Board and the contractor shall discuss how to inform patients of the proposed opt out.

(2) The contractor shall, if requested by the Local Health Board inform its registered patients of an opt out and the arrangements made for them to receive the additional service or out of hours services by -

- (a) placing a notice in the practice's waiting room; or

(b) including the information in the practice leaflet.

(3) In this paragraph "opt out" means an out of hours opt out, a permanent opt out or a temporary opt out.

## SCHEDULE 4

Regulation 21

### LIST OF PRESCRIBED MEDICAL CERTIFICATES

<i>Description of medical certificate</i>	<i>Enactment under or for the purpose of which certificate required</i>
1. To support a claim or to obtain payment either personally or by proxy; to prove incapacity to work or for self-support for the purposes of an award by the Secretary of State; or to enable proxy to draw pensions etc.	Naval and Marine Pay and Pensions Act 1865(a) Air Force (Constitution) Act 1917(b) Pensions (Navy, Army, Air Force and Mercantile Marine) Act 1939(c) Personal Injuries (Emergency Provisions) Act 1939(d) Pensions (Mercantile Marine) Act 1942(e) Polish Resettlement Act 1947(f) Social Security Administration Act 1992(g) Social Security Contributions and Benefits Act 1992(h) Social Security Act 1998(i)
2. To establish pregnancy for the purpose of obtaining welfare foods	Section 13 of the Social Security Act 1988(Schemes for distribution etc of welfare foods(j)
3. To secure registration of still-birth	Section 11 of the Births and Deaths Registration Act 1953 special provision as to still-birth(k)
4. To enable payment to be made to an institution or other person in case of mental disorder of persons entitled to payment from public funds.	Section 142 of the Mental Health Act 1983 (pay, pensions etc of mentally disordered persons)(l)
5. To establish unfitness for jury service	Juries Act 1974(m)
6. To support late application for reinstatement in civil employment or notification of non-availability to take up employment owing to sickness.	Reserve Forces (Safeguarding of Employment) Act 1985(n).

(a) 1865 c.73.

(b) 1917 c.51.

(c) 1939 c.83.

(d) 1939 c.82

(e) 1942 c.26.

(f) 1947 c.19.

(g) 1992 c.5.

(h) 1992 c.4.

(i) 1998 c.14.

(j) 1998 c.7. Section 13 was amended by the Social Security Act 1990 (c.27), Schedule 6, paragraph 8(11)(a), and the Social Security (Consequential Provisions) Act 1992 (c.6), Schedule 2, paragraph 94.

(k) 1953 c.20. Section 11 was amended by the Population (Statistics) Act 1960 (c.32) section 2 and by S.I. 1992/2395, article 2(3).

(l) 1983 c.20. Section 142 was amended by S.I. 1999/1820.

(m) 1974 c.23

(n) 1985 c.17.

7. To enable a person to be registered as an absent voter on grounds of physical incapacity	Representation of the People Act 1983(a)
8. To support applications for certificates conferring exemption from charges in respect of drugs, medicines and appliances.	National Health Service Act 1977(b)
9. To support a claim by or on behalf of a severely mentally impaired person for exemption from liability to pay the Council Tax or eligibility for a discount in respect of the amount of Council Tax payable.	Local Government Finance Act 1992(c)

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## SCHEDULE 5

Regulation 24

### FEES AND CHARGES

1. The contractor may, demand or accept, a fee or other remuneration -
- (a) from any statutory body for services rendered for the purposes of that body's statutory functions;
  - (b) from any body, employer or school for a routine medical examination of persons for whose welfare the body, employer or school is responsible, or an examination of such persons for the purpose of advising the body, employer or school of any administrative action they might take;
  - (c) for treatment which is not primary medical services or otherwise required to be provided under the contract and which is given:
    - (i) pursuant to the provisions of section 65 of the Act (accommodation and services for private patients), or
    - (ii) in a registered nursing home which is not providing services under that Act,
 if, in either case, the person administering the treatment is serving on the staff of a hospital providing services under the Act as a specialist providing treatment of the kind the patient requires and if, within 7 days of giving the treatment, the contractor or the person providing the treatment supplies the Local Health Board, on a form provided by it for the purpose, with such information about the treatment as it may require;
  - (d) under section 158 of the Road Traffic Act 1988 payment for emergency treatment of traffic casualties)(d);
  - (e) when it treats a patient under regulation 24(3), in which case it shall be entitled to demand and accept a reasonable fee (recoverable in certain circumstances under regulation 24(4)) for any treatment given, if it gives the patient a receipt;
  - (f) for attending and examining (but not otherwise treating) a patient -
    - (i) at the patient's request at a police station in connection with possible criminal proceedings against the patient,
    - (ii) at the request of a commercial, educational or not-for-profit organisation for the purpose of creating a medical report or certificate,
    - (iii) for the purpose of creating a medical report required in connection with an actual or potential claim for compensation by the patient;
  - (g) for treatment consisting of an immunisation for which no remuneration is payable by the Local Health Board and which is requested in connection with travel abroad;

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- (a) 1983 c.2.
  - (b) 1977 c.49.
  - (c) 1992 c.14.
  - (d) 1988 c.52. Section 158 was amended by S.I. 1995/889, article 3.

- (h) for prescribing or providing drugs, medicines or appliances (including a collection of such drugs medicines and appliances in the form of a travel kit) which a patient requires to have in his or her possession solely in anticipation of the onset of an ailment or occurrence of an injury while the patient is outside the United Kingdom but for which the patient is not requiring treatment when the medicine is prescribed;
- (i) for a medical examination -
  - (i) to enable a decision to be made whether or not it is inadvisable on medical grounds for a person to wear a seat belt, or
  - (ii) for the purpose of creating a report -
    - (aa) relating to a road traffic accident or criminal assault, or
    - (bb) that offers an opinion as to whether a patient is fit to travel;
- (j) for testing the sight of a person to whom none of paragraphs (a), (b) or (c) of section 38(1) of the Act (arrangements for general ophthalmic services) applies (including by reason of regulations under section 38(6) of that Act);
- (k) where it is a contractor which is authorised or required by a Local Health Board under regulation 20 of the Pharmaceutical Regulations to provide drugs, medicines or appliances to a patient and provides for that patient, otherwise than by way of pharmaceutical services, any Scheduled drug;
- (l) for prescribing or providing drugs or medicines for malaria chemoprophylaxis.

## SCHEDULE 6

Regulation 26

### OTHER CONTRACTUAL TERMS

#### PART 1

#### PROVISION OF SERVICES

##### **Premises**

1. Subject to any plan which is included in the contract pursuant to regulation 18(3), the contractor shall ensure that the premises used for the provision of services under the contract are -

- (a) suitable for the delivery of those services; and
- (b) sufficient to meet the reasonable needs of the contractor's patients.

##### **Attendance at practice premises**

2.-(1) The contractor shall take steps to ensure that any patient who -

- (a) has not previously made an appointment; and
- (b) attends at the practice premises during the normal hours for essential services,

is provided with such services by an appropriate health care professional during that surgery period except in the circumstances specified in sub-paragraph (2).

(2) The circumstances referred to in sub-paragraph (1) are that -

- (a) it is more appropriate for the patient to be referred elsewhere for services under the Act; or
- (b) the patient is then offered an appointment to attend again within a time which is appropriate and

reasonable having regard to all the circumstances and the patient's health would not thereby be jeopardised.

### **Attendance outside practice premises**

- 3.-(1) In the case of a patient whose medical condition is such that in the reasonable opinion of the contractor-
- (a) attendance on the patient is required; and
  - (b) it would be inappropriate for the patient to attend at the practice premises,

the contractor shall provide services to that patient at whichever in its judgement is the most appropriate of the places set out in sub-paragraph (2).

- (2) The places referred to in sub-paragraph (1) are -

- (a) the place recorded in the patient's medical records as being the patient's last home address;
- (b) such other place as the contractor has informed the patient and the Local Health Board is the place where it has agreed to visit and treat the patient; or
- (c) some other place in the contractor's practice area.

- (3) Nothing in this paragraph prevents the contractor from -

- (a) arranging for the referral of a patient without first seeing the patient, in a case where the medical condition of that patient makes that course of action appropriate; or
- (b) visiting the patient in circumstances where this paragraph does not place it under an obligation to do so.

### **Newly registered patients**

- 4.-(1) Where a patient has been -

- (a) accepted on a contractor's list of patients under paragraph 15; or
- (b) assigned to that list by the Local Health Board,

the contractor shall, in addition and without prejudice to its other obligations in respect of that patient under the contract, invite the patient to participate in a consultation either at its practice premises or, if the medical condition of the patient so warrants, at one of the places referred to in paragraph 3(2).

- (2) An invitation under sub-paragraph (1) shall be issued within six months of the date of the acceptance of the patient on, or their assignment to, the contractor's list.

(3) Where a patient (or, where appropriate, in the case of a patient who is a child, the child's parent) agrees to participate in a consultation mentioned in sub-paragraph (1) the contractor shall, in the course of that consultation make such inquiries and undertake such examinations as appear to it to be appropriate in all the circumstances.

### **Patients not seen within three years**

5. Where a registered patient who -

- (a) has attained the age of 16 years but has not attained the age of 75 years; and
- (b) has attended neither a consultation with, nor a clinic provided by, the contractor within the period of three years prior to the date of the patient's request,

requests a consultation the contractor shall, in addition and without prejudice to its other obligations in respect of that patient under the contract, provide such a consultation in the course of which it shall make such inquiries and undertake such examinations as appear to it to be appropriate in all the circumstances.

### **Patients aged 75 years and over**

- 6.-(1) Where a registered patient who -

- (a) has attained the age of 75 years; and
- (b) has not participated in a consultation under this paragraph within the period of twelve months prior to the date of the patient's request,

requests a consultation, the contractor shall, in addition and without prejudice to its other obligations in respect

of that patient under the contract, provide such a consultation in the course of which it shall make such inquiries and undertake such examinations as appear to it to be appropriate in all the circumstances.

(2) A consultation under sub-paragraph (1) shall take place in the home of the patient where, in the reasonable opinion of the contractor, it would be inappropriate, as a result of the patient's medical condition, for the patient to attend at the practice premises.

### **Clinical reports**

7.-(1) Where the contractor provides any clinical services, other than under a private arrangement, to a patient who is not on its list of patients, it shall, as soon as reasonably practicable, provide a clinical report relating to the consultation, and any treatment provided, to the Local Health Board.

(2) The Local Health Board shall send any report received under sub-paragraph (1)-

- (a) to the person with whom the patient is registered for the provision of essential services or their equivalent; or
- (b) if the person referred to in paragraph (a) is not known to it, the Local Health Board in whose area the patient is resident.

### **Storage of vaccines**

8. The contractor shall ensure that -

- (a) all vaccines are stored in accordance with the manufacturer's instructions ; and
- (b) all refrigerators in which vaccines are stored have a maximum/minimum thermometer and that readings are taken on all working days.

### **Infection control**

9. The contractor shall ensure that it has appropriate arrangements for infection control and decontamination.

### **Criteria for out of hours services**

10. A contractor whose contract includes the provision of out of hours services shall only be required to provide such services if, in the reasonable opinion of the contractor in the light of the patient's medical condition, it would not be reasonable in all the circumstances for the patient to wait for the services required until the next time at which the patient could obtain such services during core hours.

### **Standards for out of hours services**

11.-(1) From 1st January 2005, a contractor which provides out of hours services must, in the provision of such services, meet the quality standards set out in guidance issued by the Assembly .

### **Duty of co-operation in relation to additional, enhanced and out of hours services**

12.-(1) A contractor which does not provide to its registered patients or to persons whom it has accepted as temporary residents -

- (a) a particular additional service;
- (b) a particular enhanced service; or
- (c) out of hours services, either at all or in respect of some periods or some services,

shall comply with the requirements specified in sub-paragraph (2).

(2) The requirements referred to in sub-paragraph (1) are that the contractor shall -

- (a) co-operate with any person responsible for the provision of that service or those services;
- (b) comply in core hours with any reasonable request for information from such a person or from the Local Health Board relating to the provision of that service or those services; and
- (c) in the case of out of hours services, take reasonable steps to ensure that any patient who contacts the practice premises during the out of hours period is provided with information about how to obtain services during that period.



(3) Nothing in this paragraph shall require a contractor whose contract does not include the provision of out of hours services to make itself available during the out of hours period.

**13.** Where a contractor is to cease to be required to provide to its patients -

- (a) a particular additional service;
- (b) a particular enhanced service; or
- (c) out of hours services, either at all or in respect of some periods or some services,

it shall comply with any reasonable request for information relating to the provision of that service or those services made by the Local Health Board or by any person with whom the Local Health Board intends to enter into a contract for the provision of such services.

## **PART 2**

### **PATIENTS**

#### **List of patients**

**14.** The Local Health Board shall prepare and keep up to date a list of the patients -

- (a) who have been accepted by the contractor for inclusion in its list of patients under paragraph 15 and who have not subsequently been removed from that list under paragraphs 19 to 27; and
- (b) who have been assigned to the contractor under paragraph 32 or 33 and whose assignment has not subsequently been rescinded.

#### **Application for inclusion in a list of patients**

**15.**-(1) The contractor may, if its list of patients is open, accept an application for inclusion in its list of patients made by or on behalf of any person whether or not resident in its practice area or included, at the time of that application, in the list of patients of another contractor or provider of primary medical services.

(2) The contractor may, if its list of patients is closed, only accept an application for inclusion in its list of patients from a person who is an immediate family member of a registered patient whether or not resident in its practice area or included, at the time of that application, in the list of patients of another contractor or provider of primary medical services.

(3) Subject to sub-paragraph (4), an application for inclusion in a contractor's list of patients shall be made by delivering to the practice premises a medical card or an application signed (in either case) by the applicant or a person authorised by the applicant to sign on the applicant's behalf.

(4) An application may be made -

- (a) on behalf of any child -
  - (i) by either parent, or in the absence of both parents, the guardian or other adult who has care of the child,
  - (ii) by a person duly authorised by a local authority to whose care the child has been committed under the Children Act 1989(a), or
  - (iii) by a person duly authorised by a voluntary organisation by which the child is being accommodated under the provisions of that Act; or
- (b) on behalf of any adult who is incapable of making such an application, or authorising such an application to be made on their behalf, by a relative or the primary carer of that person.

(5) A contractor which accepts an application for inclusion in its list of patients shall notify the Local Health Board in writing as soon as possible.

(6) On receipt of a notice under sub-paragraph (5), the Local Health Board shall -

- (a) include that person in the contractor's list of patients from the date on which the notice is received; and

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(a) 1989 c.41.

- (b) notify the applicant (or, in the case of a child or incapable adult, the person making the application on their behalf) of the acceptance.

### **Temporary residents**

16.-(1) The contractor may, if its list of patients is open, accept a person as a temporary resident provided it is satisfied that the person is -

- (a) temporarily resident away from his or her normal place of residence and is not being provided with essential services (or their equivalent) under any other arrangement in the locality where he or she is temporarily residing; or
- (b) moving from place to place and not for the time being resident in any place.

(2) For the purposes of sub-paragraph (1), a person shall be regarded as temporarily resident in a place if, when that person arrives in that place, he or she intends to stay there for more than 24 hours but not more than three months.

(3) A contractor which wishes to terminate its responsibility for a person accepted as a temporary resident before the end of -

- (a) three months; or
- (b) such shorter period for which it agreed to accept that person as a patient,

shall notify that person either orally or in writing and its responsibility for that person shall cease 7 days after the date on which the notification was given.

(4) At the end of three months, or on such earlier date as its responsibility for the temporary resident has come to an end, the contractor shall notify the Local Health Board in writing of any person whom it accepted as a temporary resident.

### **Refusal of applications for inclusion in the list of patients or for acceptance as a temporary resident**

17.-(1) The contractor shall only refuse an application made under paragraph 15 or 16 if it has reasonable grounds for doing so which do not relate to the applicant's race, gender, social class, age, religion, sexual orientation, appearance, disability or medical condition.

(2) The reasonable grounds referred to in paragraph (1) shall, in the case of applications made under paragraph 15, include the ground that the applicant does not live in the contractor's practice area.

(3) A contractor which refuses an application made under paragraph 15 or 16 shall, within 14 days of its decision notify the applicant (or, in the case of a child or incapable adult, the person making the application on their behalf) in writing of the refusal and the reason for it.

(4) The contractor shall keep a written record of refusals of applications made under paragraph 15 and of the reasons for them and shall make this record available to the Local Health Board on request.

### **Patient preference of practitioner**

18.-(1) Where the contractor has accepted an application for inclusion in its list of patients, it shall -

- (a) notify the patient (or, in the case of a child or incapable adult, the person who made the application on their behalf) of the patient's right to express a preference to receive services from a particular performer or class of performer either generally or in relation to any particular condition; and
- (b) record in writing any such preference expressed by or on behalf of the patient.

(2) The contractor shall endeavour to comply with any reasonable preference expressed under sub-paragraph (1) but need not do so if the preferred performer -

- (a) has reasonable grounds for refusing to provide services to the patient; or
- (b) does not routinely perform the service in question within the practice.

### **Removal from the list at the request of the patient**

19.-(1) The contractor shall notify the Local Health Board in writing of any request for removal from its list of patients received from a registered patient.

(2) Where the Local Health Board -

- (a) receives notification from the contractor under sub-paragraph (1); or
- (b) receives a request from the patient to be removed from the contractor's list of patients

it shall remove that person from the contractor's list of patients.

(3) A removal in accordance with sub-paragraph (2) shall take effect -

- (a) on the date on which the Local Health Board receives notification of the registration of the person with another provider of essential services (or their equivalent); or
- (b) 14 days after the date on which the notification or request made under sub-paragraph (1) or (2) respectively is received by the Local Health Board,

whichever is the sooner.

(4) The Local Health Board shall, as soon as practicable, notify in writing -

- (a) the patient; and
- (b) the contractor,

that the patient's name will be or has been removed from the contractor's list of patients on the date referred to in sub-paragraph (3).

(5) In this paragraph and in paragraphs 20(1)(b) and (9), 21(6) and (7), 23 and 26, a reference to a request received from or advice, information or notification required to be given to a patient shall include a request received from or advice, information or notification required to be given to -

- (a) in the case of a patient who is a child, a parent or other person referred to in paragraph 15(4)(a); or
- (b) in the case of an adult patient who is incapable of making the relevant request or receiving the relevant advice, information or notification, a relative or the primary carer of the patient.

#### **Removal from the list at the request of the contractor**

**20.**-(1) Subject to paragraph 21, a contractor which has reasonable grounds for wishing a patient to be removed from its list of patients which do not relate to the applicant's race, gender, social class, age, religion, sexual orientation, appearance, disability or medical condition shall -

- (a) notify the Local Health Board in writing that it wishes to have the patient removed; and
- (b) subject to sub-paragraph (2), notify the patient of its specific reasons for requesting removal.

(2) Where in the reasonable opinion of the contractor-

- (a) the circumstances of the removal are such that it is not appropriate for a more specific reason to be given; and
- (b) there has been an irrevocable breakdown in the relationship between the patient and the contractor,

the reason given under sub-paragraph (1) may consist of a statement that there has been such a breakdown.

(3) Except in the circumstances specified in sub-paragraph (4) a contractor may only request a removal under sub-paragraph (1), if, within the period of 12 months prior to the date of its request to the Local Health Board, it has warned the patient that the patient is at risk of removal and has explained to the patient the reasons for this.

(4) The circumstances referred to in sub-paragraph (3) are that -

- (a) The reason for removal relates to a change of address;
- (b) The contractor has reasonable grounds for believing that the issue of such a warning would-
  - (i) be harmful to the physical or mental health of the patient, or
  - (ii) put at risk the safety of one or more of the persons specified in sub-paragraph (5); or;
- (c) it is, in the opinion of the contractor, not otherwise reasonably practicable for a warning to be given.

(5) The persons referred to in sub-paragraph (4) are -

- (a) the contractor, where it is an individual medical practitioner;
- (b) in the case of a contract with two or more individuals practising in partnership, a partner in that partnership;
- (c) in the case of a contract with a company, a legal and beneficial owner of shares in that company;

- (d) a member of the contractor's staff;
- (e) a person engaged by the contractor to perform or assist in the performance of services under the contract:  
or
- (f) any other person present-
  - (i) on the practice premises, or
  - (ii) in the place where services are being provided under the contract.

(6) The contractor shall record in writing-

- (a) the date of any warning given in accordance with sub-paragraph (3) and the reasons for giving such a warning as explained to the patient; or
- (b) the reason why no such warning was given.

(7) The contractor shall keep a written record of removals under this paragraph which shall include -

- (a) the reason for removal given to the patient;
- (b) the circumstances of the removal; and
- (c) in cases where sub-paragraph (2) applies, the grounds for a more specific reason not being appropriate,

and shall make this record available to the Local Health Board on request.

(8) A removal requested in accordance with sub-paragraph (1) shall, subject to sub-paragraph (9), take effect from -

- (a) the date on which the Local Health Board receives notification of the registration of the person with another provider of essential services (or their equivalent); or
- (b) the eighth day after the Local Health Board receives the notice referred to in sub-paragraph (1)(a),

whichever is the sooner.

(9) Where, on the date on which the removal would take effect under sub-paragraph (8), the contractor is treating the patient at intervals of less than seven days, the contractor shall notify the Local Health Board in writing of the fact and the removal shall take effect -

- (a) on the eighth day after the Local Health Board receives notification from the contractor that the person no longer needs such treatment; or
- (b) on the date on which the Local Health Board receives notification of the registration of the person with another provider of essential services (or their equivalent),

whichever is the sooner.

(10) The Local Health Board shall notify in writing -

- (a) the patient; and
- (b) the contractor

that the patient's name has been or will be removed from the contractor's list of patients on the date referred to in sub-paragraph (8) or (9).

**Removals from the list of patients who are violent**

21.-(1) A contractor which wishes a patient to be removed from its list of patients with immediate effect on the grounds that -

- (a) the patient has committed an act of violence against any of the persons specified in sub-paragraph (2) or behaved in such a way that any such person has feared for his or her safety; and
- (b) it has reported the incident to the police,

shall notify the Local Health Board in accordance with sub-paragraph (3).

(2) The persons referred to in sub-paragraph (1) are -

- (a) the contractor where it is an individual medical practitioner;
- (b) in the case of a contract with two or more individuals practising in partnership, any partner in that partnership;

- (c) in the case of a contract with a company, a legal and beneficial owner of shares in that company;
- (d) a member of the contractor's staff;
- (e) a person engaged by the contractor to perform or assist in the performance of services under the contract;  
or
- (f) any other person present-
  - (i) on the practice premises or
  - (ii) in the place where services were provided to the patient under the contract.

(3) Notification under sub-paragraph (1) may be given by any means including telephone or fax but if not given in writing shall subsequently be confirmed in writing within seven days (and for this purpose a faxed notification is not a written one).

(4) The Local Health Board shall acknowledge in writing receipt of a request from the contractor under sub-paragraph (1).

- (5) A removal requested in accordance with sub-paragraph (1) shall take effect at the time that the contractor -
- (a) makes the telephone call to the Local Health Board; or
  - (b) sends or delivers the notification to the Local Health Board.

(6) Where, pursuant to this paragraph, the contractor has notified the Local Health Board that it wishes to have a patient removed from its list of patients, it shall inform the patient concerned unless -

- (a) it is not reasonably practicable for it to do so; or
- (b) it has reasonable grounds for believing that to do so would -
  - (i) be harmful to the physical or mental health of the patient; or
  - (ii) put at risk the safety of the contractor or other persons,
  - (iii) put at risk the safety of one or more of the persons specified in sub-paragraph (2).

(7) Where the Local Health Board has removed a patient from the contractor's list of patients in accordance with sub-paragraph (5) it shall give written notice of the removal to that patient.

(8) Where a patient is removed from the contractor's list of patient in accordance with this paragraph, the contractor shall record in the patient's medical records that the patient has been removed under this paragraph and the circumstances leading to the patient's removal.

### **Removals from lists if patients registered elsewhere**

22.-(1) The Local Health Board shall remove a patient from the contractor's list of patients if -

- (a) the patient has subsequently been registered with another provider of essential services (or their equivalent) in the area of the Local Health Board; or
- (b) it has received notice from another Local Health Board, a Primary Care Trust, a Health Board or a Health and Social Services Board that the patient has subsequently been registered with a provider of essential services (or their equivalent) outside the area of the Local Health Board.

(2) A removal in accordance with sub-paragraph (1) shall take effect -

- (a) on the date on which the Local Health Board receives notification of the registration of the person with the new provider; or
- (b) with the consent of the Local Health Board, on such other date as has been agreed between the contractor and the new provider.

(3) The Local Health Board shall notify the contractor in writing of persons removed from its list of patients under sub-paragraph (1).

### **Removals from the list of patients who have moved**

23.-(1) Subject to sub-paragraph (2), where the Local Health Board is satisfied that a person on the contractor's list of patients has moved and no longer resides in that contractor's practice area, the Local Health Board shall -

- (a) inform that patient and the contractor that the contractor is no longer obliged to visit and treat the person;
- (b) advise the patient in writing either to obtain the contractor's agreement to the continued inclusion of the

person on its list of patients or to apply for registration with another provider of essential services (or their equivalent); and

- (c) inform the patient that if, after the expiration of 30 days from the date of the advice mentioned in paragraph (b), the patient has not acted in accordance with the advice and informed it accordingly, the Local Health Board will remove the patient from the contractor's list of patients.

(2) If, at the expiration of the period of 30 days referred to in sub-paragraph (1)(c), the Local Health Board has not been notified of the action taken, it shall remove the patient from the contractor's list of patients and inform the patient and the contractor accordingly.

**24.** Where the address of a patient who is on the contractor's list of patients is no longer known to the Local Health Board, the Local Health Board shall -

- (a) give to the contractor notice in writing that it intends, at the end of the period of six months commencing with the date of the notice, to remove the patient from the contractor's list of patients; and
- (b) at the end of that period, remove the patient from the contractor's list of patients unless, within that period, the contractor satisfies the Local Health Board that it is still responsible for providing essential services to that patient.

### **Removals from the list of patients absent from the United Kingdom etc**

**25.**-(1) The Local Health Board shall remove a patient from the contractor's list of patients where it receives notification that that patient -

- (a) intends to be away from the United Kingdom for a period of at least three months;
- (b) is in Her Majesty's Forces;
- (c) is serving a prison sentence of more than two years or sentences totalling in the aggregate more than that period;
- (d) has been absent from the United Kingdom for a period of more than three months; or
- (e) has died.

(2) A removal in accordance with sub-paragraph (1) shall take effect -

- (a) in the cases referred to in sub-paragraph (1)(a) to (c) from the date of the departure, enlistment or imprisonment or the date on which the Local Health Board first receives notification of the departure, enlistment or imprisonment whichever is the later; or
- (b) in the cases referred to in sub-paragraph (1) (d) and (e) from the date on which the Local Health Board first receives notification of the absence or death.

(3) The Local Health Board shall notify the contractor in writing of patients removed from its list of patients under sub-paragraph (1).

### **Removals from the list of patients accepted elsewhere as temporary residents**

**26.**-(1) The Local Health Board shall remove from the contractor's list of patients a patient who has been accepted as a temporary resident by another contractor or other provider of essential services (or their equivalent) where it is satisfied, after due inquiry -

- (a) that the patient's stay in the place of temporary residence has exceeded three months; and
- (b) that the patient has not returned to the patient's normal place of residence or any other place within the contractor's practice area.

(2) The Local Health Board shall notify in writing of a removal under sub-paragraph (1) -

- (a) the contractor; and
- (b) where practicable, the patient.

(3) A notification to the patient under sub-paragraph (2)(b) shall inform the patient of -

- (a) the patient's entitlement to make arrangements for the provision to the patient of essential services (or their equivalent), including by the contractor by which the patient has been treated as a temporary resident; and
- (b) the name and address of the Local Health Board in whose area the patient is resident.

### **Removals from the list of pupils etc of a school**

27.-(1) Where the contractor provides essential services under the contract to persons on the grounds that they are pupils at or staff or residents of a school, the Local Health Board shall remove from the contractor's list of persons any such patients who do not appear on particulars of persons who are pupils at or staff or residents of that school provided by that school.

(2) Where the Local Health Board has made a request to a school to provide the particulars mentioned in sub-paragraph (1) and has not received them, it shall consult the contractor as to whether it should remove from its list of patients any persons appearing on that list as pupils at, or staff or residents of that school.

(3) The Local Health Board shall notify the contractor in writing of patients removed from its list of patients under sub-paragraph (1).

### **Termination of responsibility for patients not registered with the contractor**

28.-(1) Where a contractor -

- (a) has received an application for the provision of medical services other than essential services -
  - (i) from a person who is not included in its list of patients,
  - (ii) from a person whom it has not accepted as a temporary resident, or
  - (iii) on behalf of a person mentioned in sub-paragraph (i) or (ii), from one of the persons specified in paragraph 15(4); and
- (b) has accepted that person as a patient for the provision of the service in question,

its responsibility for that patient shall be terminated in the circumstances referred to in sub-paragraph (2).

(2) The circumstances referred to in sub-paragraph (1) are -

- (a) the patient informs the contractor that he or she no longer wishes it to be responsible for provision of the service in question;
- (b) in cases where the contractor has reasonable grounds for terminating its responsibility which do not relate to the person's race, gender, social class, age, religion, sexual orientation, appearance, disability or medical condition, the contractor informs the patient that it no longer wishes to be responsible for providing the patient with the service in question; or
- (c) it coming to the notice of the contractor that the patient -
  - (i) no longer resides in the area for which the contractor has agreed to provide the service in question, or
  - (ii) is no longer included in the list of patients of another contractor to whose registered patients the contractor has agreed to provide that service.

(3) A contractor which wishes to terminate its responsibility for a patient under sub-paragraph (2)(b) shall notify the patient of the termination and the reason for it.

(4) The contractor shall keep a written record of terminations under this paragraph and of the reasons for them and shall make this record available to the Local Health Board on request.

(5) A termination under sub-paragraph (2)(b) shall take effect -

- (a) from the date on which the notice is given where the grounds for termination are those specified in paragraph 21(1); or
- (b) in all other cases, 14 days from the date on which the notice is given.

### **Closure of lists of patients**

29.-(1) A contractor which wishes to close its list of patients shall notify the Local Health Board in writing to that effect.

(2) Within a period of 7 days beginning with the date of receipt of the notification referred to in sub-paragraph (1) or, if that is not reasonably practicable, as soon as is practicable thereafter, the Local Health Board shall enter into discussions with the contractor concerning the support which the Local Health Board may give the contractor, or other changes which the Local Health Board or the contractor may make, which would enable the contractor to keep its list of patients open.

(3) In the discussions referred to in sub-paragraph (2) both parties shall use reasonable endeavours to achieve the aim of keeping the contractor's list of patients open.

(4) The discussions mentioned in sub-paragraph (2) shall be completed within a period of 28 days beginning with the date of the Local Health Board's receipt of the notification referred to in sub-paragraph (1), or within such longer period as the parties may agree.

(5) If, following the discussions mentioned in sub-paragraph (2), the Local Health Board and the contractor reach agreement that the contractor's list of patients should remain open, the Local Health Board shall send full details of the agreement in writing to the contractor.

(6) The Local Health Board and the contractor shall comply with the terms of an agreement reached as mentioned in sub-paragraph (5).

(7) If, following the discussions mentioned in sub-paragraph (2) -

- (a) the Local Health Board and the contractor reach agreement that the contractor's list of patients should close; or
- (b) the Local Health Board and the contractor fail to reach agreement and the contractor still wishes to close its list of patients,

the contractor shall send a closure notice to the Local Health Board.

(8) A closure notice shall be submitted in the form specified in Schedule 8, and shall include the following details which (in a case falling within sub-paragraph (7)(a)) have been agreed between the parties or (in a case falling within sub-paragraph (7)(b)) are proposed by the contractor -

- (a) the period of time (which may not exceed 12 months) for which the contractor's list of patients will be closed;
- (b) the current number of the contractor's registered patients;
- (c) the number of registered patients (lower than the current number of such patients, and expressed either in absolute terms or as a percentage of the number of such patients specified pursuant to paragraph (b)) which, if that number were reached, would trigger the re-opening of the contractor's list of patients;
- (d) the number of registered patients (expressed either in absolute terms or as a percentage of the number of such patients specified pursuant to paragraph (b)) which, if that number were reached, would trigger the re-closure of the contractor's list of patients; and
- (e) any withdrawal from or reduction in provision of any additional or enhanced services which had previously been provided under the contract.

(9) The Local Health Board shall forthwith acknowledge receipt of the closure notice in writing to the contractor.

(10) Before the Local Health Board reaches a decision as to whether to approve or reject the closure notice under sub-paragraph (12), the Local Health Board and the contractor may enter into further discussions concerning the details of the closure notice referred to in sub-paragraph (8), with a view to reaching agreement; and, in particular, if the parties are unable to reach agreement regarding the period of time for which the contractor's list of patients will be closed, that period shall be 12 months.

(11) A contractor may not withdraw a closure notice for a period of three months beginning with the date on which the Local Health Board has received the notice, unless the Local Health Board has agreed otherwise in writing.

(12) Within a period of 14 days beginning with the date of receipt of the closure notice, the Local Health Board shall -

- (a) approve the closure notice; or
- (b) reject the closure notice,

and shall notify the contractor of its decision in writing as soon as possible.

(13) Approval of the closure notice under sub-paragraph (12)(a) includes approval of the details specified in accordance with sub-paragraph (8) (or, where those details are revised following discussions under sub-paragraph (10), approval of those details as so revised).



### **Approval of closure notice by the Local Health Board**

30.-(1) If the Local Health Board approves the closure notice in accordance with paragraph 29(12)(a), the contractor shall close its list of patients -

- (a) with effect from a date agreed between the Local Health Board and the contractor; or
- (b) if no such agreement has been reached, with effect from the date on which the contractor receives notification of the Local Health Board's decision to approve the closure notice.

(2) Subject to sub-paragraph (3), the contractor's list of patients shall remain closed for the period specified in the closure notice in accordance with paragraph 29(8)(a) (or, where the period of 12 months specified in paragraph 29(10) applies, for that period).

(3) The contractor's list of patients shall re-open before the expiry of the period mentioned in sub-paragraph (2) if -

- (a) the number of the contractor's registered patients falls to the number specified in the closure notice in accordance with paragraph 29(8)(c); or
- (b) the Local Health Board and the contractor agree that the list of patients should re-open.

(4) If the contractor's list of patients has re-opened pursuant to paragraph (3)(a), it shall nevertheless close again if, during the period specified in the closure notice in accordance with paragraph 29(8)(a) (or, where the period of 12 months specified in paragraph 29(10) applies, during that period) the number of the contractor's registered patients rises to the number specified in the closure notice in accordance with paragraph 28(8)(d). (if any) for the area of the Local Health Board.

(5) Except in cases where the contractor's list of patients is already open pursuant to sub-paragraph (3), the Local Health Board shall notify the contractor in writing between seven and fourteen days before the expiry of the period of closure specified in sub-paragraph (2), confirming the date on which the contractor's list of patients will re-open.

(6) Where the details specified in the closure notice in accordance with paragraph 29(8) have been revised following discussions under paragraph 29(10), references in this paragraph to details specified in the closure notice are references to those details as so revised.

### **Rejection of closure notice by the Local Health Board**

31.-(1) This regulation applies where the Local Health Board rejects the closure notice in accordance with paragraph 29(12) (b).

(2) The contractor and the Local Health Board may not refer the matter for determination in accordance with the NHS dispute resolution procedure (or, where applicable, commence court proceedings) until the assessment panel has given its determination in accordance with the following sub-paragraphs.

(3) The Local Health Board must ensure that the assessment panel is appointed as soon as is practicable to consider and determine whether the contractor should be permitted to close its list of patients, and if so, the terms on which it should be permitted to do so.

(4) The Local Health Board shall provide the assessment panel with such information as the assessment panel may reasonably require to enable it to reach a determination and shall include in such information any written observations received from the contractor.

(5) The members of the assessment panel shall be -

- (a) the Chief Executive of the Local Health Board of which the assessment panel is a committee or sub-committee;
- (b) a person representative of patients in an area other than that of the Local health Board which is a party to the contract; and
- (c) a person representative of a Local Medical Committee which does not represent practitioners in the area of the Local Health Board which is a party to the contract.

(6) At least one member of the assessment panel shall visit the contractor before reaching a determination under sub-paragraph (7).

(7) Within the period of 28 days beginning with the date on which the Local Health Board rejected the closure notice, the assessment panel shall -

- (a) approve the list closure; or
- (b) reject the list closure,

and shall notify the Local Health Board and the contractor of its determination in writing as soon as possible.

(8) Where the assessment panel determines in accordance with sub-paragraph (7)(a) that the contractor's list of patients should close, it shall specify -

- (a) a date from which the closure shall take effect, which must be within a period of 7 days beginning with the date of the assessment panel's determination; and
- (b) those details specified in paragraph 29(8).

(9) Where the assessment panel determines in accordance with sub-paragraph (7)(b) that the contractor's list of patients may not close, that list shall remain open, and the Local Health Board and the contractor shall enter into discussions with a view to ensuring that the contractor receives support from the Local Health Board which will enable it to continue to provide services safely and effectively.

(10) Where the assessment panel determines in accordance with sub-paragraph (7)(b) that the contractor's list of patients may not close, the contractor may not submit a further closure notice as described in paragraph 29 until -

- (a) the expiry of a period of three months beginning with the date of the assessment panel's determination; or
- (b) (if applicable) the final determination of the NHS dispute resolution procedure (or any court proceedings),

whichever is the later, unless there has been a change in the circumstances of the contractor which affects its ability to deliver services under the contract.

#### **Assignment of patients to lists: open lists**

**32.**-(1) A Local Health Board may, subject to paragraph 34, assign a new patient to a contractor whose list of patients is open.

(2) In this paragraph and in paragraphs 33 and 35 to 37, a "new" patient means a person who -

- (a) is resident (whether or not temporarily) within the area of the Local Health Board;
- (b) has been refused inclusion in a list of patients of, or has not been accepted as a temporary resident by, a contractor whose premises are within such an area; and
- (c) wishes to be included in the list of patients of a contractor whose practice premises are within that area.

#### **Assignment of patients to lists: closed lists**

**33.**-(1) A Local Health Board may not assign a new patient to a contractor which has closed its list of patients except in the circumstances specified in sub-paragraph (2).

(2) A Local Health Board may, subject to paragraph 34, assign a new patient to a contractor whose practice premises are within the Local Health Board's area and which has closed its list of patients, if -

- (a) most or all of the providers of essential services (or their equivalent) whose practice premises are within the Local Health Board's area have closed their lists of patients;
- (b) the assessment panel has determined under paragraph 35(7) that patients may be assigned to the contractor in question, and that determination has not been overturned either by a determination of the Assembly under paragraph 36(13) or (where applicable) by a court; and
- (c) the Local Health Board has entered into discussions with the contractor in question regarding the assignment of a patient if such discussions are required under paragraph 37.

#### **Factors relevant to assignments**

**34.** In making an assignment to a contractor under paragraph 32 or 33, the Local Health Board shall have regard to -

- (a) the wishes and circumstances of the patient to be assigned;
- (b) the distance between the patient's place of residence and the contractor's practice premises;
- (c) whether, during the six months ending on the date on which the application for assignment is received by the Local Health Board, the patient's name has been removed from the list of patients of any contractor in the area of the Local Health Board under paragraph 20 or its equivalent provision in relation to a section

28C provider in the area of the Local Health Board;

- (d) whether the patient's name has been removed from the list of patients of any contractor in the area of the Local Health Board under paragraph 21 or its equivalent provision in relation to a section 28C provider in the area of the Local Health Board and, if so, whether the contractor has appropriate facilities to deal with such a patient;
- (e) such other matters as the Local Health Board considers to be relevant.

#### **Assignments to closed lists: determinations of the assessment panel**

**35.**-(1) This paragraph applies where most or all of the providers of essential services (or their equivalent) whose practice premises are within the area of a Local Health Board have closed their lists of patients.

(2) If the Local Health Board wishes to assign new patients to contractors which have closed their lists of patients, it must prepare a proposal to be considered by the assessment panel which must include details of those contractors to which the Local Health Board wishes to assign patients.

(3) The Local Health Board must ensure that the assessment panel is appointed to consider and determine its proposal made under sub-paragraph (2), and the composition of the assessment panel shall be as described in paragraph 31(5).

(4) The Local Health Board shall notify in writing -

- (a) the Assembly;
- (b) contractors or section 28C providers whose practice premises are within the Local Health Board's area which -
  - (i) have closed their list of patients, and
  - (ii) may, in the opinion of the Local Health Board, be affected by the determination of the assessment panel; and
- (c) the Local Medical Committee (if any) for the area of the Local Health Board.

that it has referred the matter to the assessment panel.

(5) In reaching its determination, the assessment panel shall have regard to relevant factors including -

- (a) whether the Local Health Board has attempted to secure the provision of essential services (or their equivalent) for new patients other than by means of their assignment to contractors with closed lists of patients; and
- (b) the workload of those contractors likely to be affected by any decision to assign such patients to their list of patients.

(6) The assessment panel shall reach a determination within the period of 28 days beginning with the date on which the panel was appointed.

(7) The assessment panel shall determine whether the Local Health Board may assign patients to contractors which have closed their lists of patients; and if it determines that the Local Health Board may make such assignments, it shall also determine those contractors to which patients may be assigned.

(8) The assessment panel may determine that the Local Health Board may assign patients to contractors other than those contractors specified by the Local Health Board in its proposal under sub-paragraph (2), as long as the contractors were notified under sub-paragraph (4)(b).

(9) The assessment panel's determination shall include its comments on the matters specified in sub-paragraph (5), and shall be notified in writing to -

- (a) the Assembly; and
- (b) those contractors which were notified under sub-paragraph (4)(b).

#### **Assignments to closed lists: NHS dispute resolution procedure relating to determinations of the assessment panel**

**36.**-(1) Where an assessment panel makes a determination under paragraph 35(7) that the Local Health Board may assign new patients to contractors which have closed their lists of patients, any contractor specified in that determination may refer the matter to the Assembly to review the determination of the assessment panel.

(2) Where a matter is referred to the Assembly in accordance with sub-paragraph (1), it shall be reviewed in accordance with the procedure specified in the following sub-paragraphs.

(3) Where more than one contractor specified in the determination in accordance with paragraph 35(7) wishes to refer the matter for dispute resolution, those contractors may, if they all agree, refer the matter jointly, and in that case the Assembly shall review the matter in relation to those contractors together.

(4) Within the period of 7 days beginning with the date of the determination by the assessment panel in accordance with paragraph 35(7), the contractor (or contractors) shall send to the Assembly a written request for dispute resolution which shall include or be accompanied by -

- (a) the names and addresses of the parties to the dispute;
- (b) a copy of the contract (or contracts); and
- (c) a brief statement describing the nature and circumstances of the dispute.

(5) Within the period of 7 days beginning with the date on which the matter was referred to it, the Assembly shall -

- (a) give to the parties notice in writing that it is dealing with the matter; and
- (b) include with the notice a written request to the parties to make in writing within a specified period any representations which they may wish to make about the dispute.

(6) The Assembly shall give, with the notice given under sub-paragraph (5), to the party other than the one which referred the matter to dispute resolution a copy of any document by which the dispute was referred to dispute resolution.

(7) The Assembly shall, upon receiving any representations from a party, give a copy of them to the other party, and shall in each case request (in writing) a party to which a copy of the representations is given to make within a specified period any written observations which it wishes to make on those representations.

(8) For the purpose of assisting it in its consideration of the matter, the Assembly may -

- (a) invite representatives of the parties to appear before it to make oral representations either together or, with the agreement of the parties, separately, and may in advance provide the parties with a list of matters or questions to which it wishes them to give special consideration; or
- (b) consult other persons whose expertise it considers will assist it in its consideration of the dispute.

(9) Where the Assembly consults another person under sub-paragraph (8)(b), it shall notify the parties accordingly in writing and, where it considers that the interests of any party might be substantially affected by the result of the consultation, it shall give to the parties such opportunity as it considers reasonable in the circumstances to make observations on those results.

(10) In considering the dispute, the Assembly shall consider -

- (a) any written representations made in response to a request under sub-paragraph (5)(b), but only if they are made within the specified period;
- (b) any written observations made in response to a request under sub-paragraph (7), but only if they are made within the specified period;
- (c) any oral representations made in response to an invitation under sub-paragraph (8)(a);
- (d) the results of any consultation under sub-paragraph (8)(b); and
- (e) any observations made in accordance with an opportunity given under sub-paragraph (9).

(11) Subject to the other provisions of this paragraph and to any agreement by the parties, the Assembly shall have wide discretion in determining the procedure of the dispute resolution to ensure the just, expeditious, economical and final determination of the dispute.

(12) In this paragraph, "specified period" means such period as the Assembly shall specify in the request, being not less than one, nor more than two, weeks beginning with the date on which the notice referred to is given, but the Assembly may, if the period for determination of the dispute has been extended in accordance with sub-paragraph (16), extend any such period (even after it has expired) and, where it does so, a reference in this paragraph to the specified period is to the period as so extended.

(13) Subject to sub-paragraph (16), within the period of 21 days beginning with the date on which the matter was referred to him, the Assembly shall determine whether the Local Health Board may assign patients to contractors which have closed their lists of patients; and if it determines that the Local Health Board may make such assignments, it shall also determine those contractors to which patients may be assigned.

(14) The Assembly may not determine that patients may be assigned to a contractor which was not specified in the determination of the assessment panel under paragraph 35(7).

(15) In the case of a matter referred jointly by contractors in accordance with sub-paragraph (3), the Assembly may determine that patients may be assigned to one, some or all of the contractors which referred the matter.

(16) The period of 21 days referred to in sub-paragraph (13) may be extended (even after it has expired) by a further specified number of days if an agreement to that effect is reached by -

- (a) the Assembly;
- (b) the Local Health Board; and
- (c) the contractor (or contractors) which referred the matter to dispute resolution.

(17) The Assembly shall record its determination, and the reasons for it, in writing and shall give notice of the determination (including the record of the reasons) to the parties.

### **Assignments to closed lists: assignments of patients by a Local Health Board**

37.-(1) Before the Local Health Board may assign a new patient to a contractor, it shall, subject to sub-paragraph (3), enter into discussions with that contractor regarding additional support that the Local Health Board can offer the contractor, and the Local Health Board shall use its best endeavours to provide appropriate support.

(2) In the discussions referred to in sub-paragraph (1), both parties shall use reasonable endeavours to reach agreement.

(3) The requirement in sub-paragraph (1) to enter into discussions applies -

- (a) to the first assignment of a patient to a particular contractor; and
- (b) to any subsequent assignment to that contractor to the extent that it is reasonable and appropriate having regard to the numbers of patients who have been or may be assigned to it and the period of time since the last discussions under sub-paragraph (1) took place.

## **PART 3**

### **PRESCRIBING AND DISPENSING**

#### **Prescribing**

38. The contractor shall ensure that any prescription form or repeatable prescription for drugs, medicines or appliances issued by a prescriber complies as appropriate with the requirements in paragraphs 39 and 41 to 44.

39.-(1) Subject to paragraphs 42 and 43, a prescriber shall order any drugs, medicines or appliances which are needed for the treatment of any patient who is receiving treatment under the contract by issuing to that patient a prescription form or a repeatable prescription and such a prescription form or repeatable prescription shall not be used in any other circumstances.

(2) A prescriber may order drugs, medicines or appliances on a repeatable prescription only where the drugs, medicines or appliances are to be provided more than once.

(3) In issuing any such prescription form or repeatable prescription the prescriber shall himself or herself sign the prescription form or repeatable prescription in ink with his or her initials, or forenames, and surname in his or her own handwriting and not by means of a stamp and shall so sign only after particulars of the order have been inserted in the prescription form or repeatable prescription, and -

- (a) the prescription form or repeatable prescription shall not refer to any previous prescription form or repeatable prescription; and
- (b) a separate prescription form or repeatable prescription shall be used for each patient, except where a bulk prescription is issued for a school or institution under paragraph 44.

(4) Where a prescriber orders a drug specified in Schedules 2 to 5 to the Misuse of Drugs Regulations 2001 (controlled drugs to which regulations 14, 15, 16, 18, 19, 20, 21, 22, 23, 24, 26 and 27 of those Regulations apply)(a) for supply by instalments for treating addiction to any drug specified in that Schedule, he or she shall:

- (a) use only the prescription form provided specially for the purposes of supply by instalments;
- (b) specify the number of instalments to be dispensed and the interval between each instalment; and
- (c) order only such quantity of the drug as will provide treatment for a period not exceeding 14 days.

(5) The prescription form provided specially for the purpose of supply by instalments shall not be used for any purpose other than ordering drugs in accordance with sub-paragraph (4).

(6) In a case of urgency a prescriber may request a chemist to dispense a drug or medicine before a prescription form or repeatable prescription is issued, only if:

- (a) that drug or medicine is not a Scheduled drug;
- (b) that drug is not a controlled drug within the meaning of the Misuse of Drugs Act 1971(b), other than a drug which is for the time being specified in Schedules 4 or 5 to the Misuse of Drugs Regulations 2001(c); and
- (c) the prescriber undertakes to furnish the chemist, within 72 hours, with a prescription form or repeatable prescription completed in accordance with sub-paragraph (3).

(7) In a case of urgency a prescriber may request a chemist to dispense an appliance before a prescription form or repeatable prescription is issued only if -

- (a) that appliance does not contain a Scheduled drug or a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 5 to the Misuse of Drugs Regulations 2001;
- (b) in the case of a restricted availability appliance, the patient is a person, or it is for a purpose, specified in the Drug Tariff; and
- (c) the prescriber undertakes to furnish the chemist, within 72 hours, with a prescription form or repeatable prescription completed in accordance with sub-paragraph (3).

### **Repeatable prescribing services**

**40.**-(1) The contractor may only provide repeatable prescribing services to any person on its list of patients if it -

- (a) satisfies the conditions in sub-paragraph (2); and
- (b) has notified the Local Health Board of its intention to provide repeatable prescribing services in accordance with sub-paragraphs (3) and (4).

(2) The conditions referred to in sub-paragraph (1)(a) are -

- (a) the contractor holds a contract with a Local Health Board specified in Schedule 9;
- (b) the contractor has access to computer systems and software which enable it to issue repeatable prescriptions and batch issues; and
- (c) the practice premises at which the repeatable prescribing services are to be provided are located in an area of the Local Health Board in which there is also located the premises of at least one chemist who has undertaken to provide, or has entered into an arrangement to provide, repeat dispensing services.

(3) The notification referred to in sub-paragraph (1)(b) is a notification, in writing, by the contractor to the Local Health Board that it -

- (a) wishes to provide repeatable prescribing services; and
- (b) intends to begin to provide those services from a specified date; and
- (c) satisfies the conditions in paragraph (2).

(4) The date specified by the contractor pursuant to sub-paragraph (3)(b) must be at least ten days after the date on which the notification specified in sub-paragraph (1) is given.

(5) Nothing in this paragraph requires a contractor or prescriber to provide repeatable prescribing services to any person.

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(a) S.I. 2001/3998; Schedule 2 was amended by S.I. 2003/1432.

(b) 1971 c.38.

(c) Schedule 4 was amended by S.I. 2003/1432.

- (6) A prescriber may only provide repeatable prescribing services to a person on a particular occasion if -
- (a) that person has agreed to receive such services on that occasion; and
  - (b) the prescriber considers that it is clinically appropriate to provide such services to that person on that occasion.
- (7) The contractor may not provide repeatable prescribing services to any patient of its to whom-
- (a) it is authorised or required by the Local Health Board to provide dispensing services under paragraph 47; or
  - (b) any of the persons specified in sub-paragraph (8) is authorised or required by the Local Health Board under regulation 20 of the Pharmaceutical Regulations to provide pharmaceutical services.
- (8) The persons referred to in paragraph (7) are -
- (a) in the case of a contract with an individual medical practitioner, that medical practitioner;
  - (b) in the case of two or more individuals practising in partnership, any medical practitioner who is a partner;
  - (c) in the case of a contract with a company any medical practitioner who is a legal and beneficial shareholder in that company; or
  - (d) any medical practitioner employed by the contractor.

### **Repeatable prescriptions**

41.-(1) A prescriber who issues a repeatable prescription must at the same time issue the appropriate number of batch issues.

(2) A prescriber who has provided repeatable prescribing services to a person must, as soon as is practicable, notify that person, and make reasonable efforts to contact the chemist providing repeat dispensing services to that person, if -

- (a) the prescriber makes any change to the type, quantity, strength or dosage of drugs, medicines or appliances ordered on that person's repeatable prescription; or
- (b) the prescriber considers that it is no longer appropriate or safe for that person to receive the drugs, medicines or appliances ordered on the person's repeatable prescription, or no longer appropriate or safe for the person to continue to receive repeatable prescribing services.

(3) If a prescriber provides repeatable prescribing services to a person in respect of whom the prescriber has previously issued a repeatable prescription which has not yet expired (for example, because that person wishes to obtain the drugs, medicines or appliances from a different chemist), the prescriber must make reasonable efforts to notify the chemist which has in its possession the repeatable prescription which is no longer required.

(4) If a prescriber has issued a repeatable prescription in respect of a person, and (before the expiry of that repeatable prescription) it comes to the prescriber's notice that that person has been removed from the list of patients of the contractor on whose behalf the prescription was issued, that prescriber must -

- (a) notify that person; and
- (b) make reasonable efforts to notify the chemist who has been providing repeat dispensing services to that person,

that the repeatable prescription should no longer be used to obtain or provide repeat dispensing services.

### **Restrictions on prescribing by medical practitioners**

42.-(1) In the course of treating a patient to whom a medical practitioner is providing treatment under the contract, a medical practitioner shall not order on a prescription form or repeatable prescription a drug, medicine or other substance specified in any directions given by the Assembly under section 28U of the Act (GMS contracts : prescription of drugs etc)(a) as being drugs, medicines or other substances which may not be ordered for patients in the provision of medical services under the contract but may, subject to regulation 24(2)(b), prescribe such a drug medicine or other substance for that patient in the course of that treatment under a private arrangement.

(2) In the course of treating a patient to whom a medical practitioner is providing treatment under the contract, a medical practitioner shall not order on a prescription form or repeatable prescription a drug, medicine or other substance specified in any directions given by the Assembly under section 28U of the Act as being a drug medicine or other substance which can only be ordered for specified patients and specified purposes unless:

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(a) Section 284 was inserted by section 175(1) of the 2003 Act.

- (a) that patient is a person of the specified description;
- (b) that drug medicine or other substance is prescribed for that patient only for the specified purpose; and
- (c) the practitioner endorses the form with the reference "SLS",

but may, subject to regulation 24(2)(b), prescribe such a drug for that patient in the course of that treatment under a private arrangement.

(3) In the course of treating a patient to whom a medical practitioner is providing treatment under the contract, a medical practitioner shall not order on a prescription form or repeatable prescription a restricted availability appliance unless -

- (a) the patient is a person, or it is for a purpose, specified in the Drug Tariff; and
- (b) the practitioner endorses the face of the form with the reference "SLS",

but may, subject to regulation 24(2)(b), prescribe such an appliance for that patient in the course of that treatment under a private arrangement.

(4) In the course of treating a patient to whom a medical practitioner is providing treatment under the contract, a medical practitioner shall not order on a repeatable prescription a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001, but may, subject to regulation 24(2)(b), prescribe such a drug for that patient in the course of that treatment under a private arrangement.

### **Restrictions on prescribing by supplementary prescribers**

**43.**-(1) The contractor shall have arrangements in place to secure that a supplementary prescriber person will -

- (a) give a prescription for a prescription only medicine;
- (b) administer a prescription only medicine for parenteral administration; or
- (c) give directions for the administration of a prescription only medicine for parenteral administration,

as a supplementary prescriber only under the conditions set out in sub-paragraph (2).

(2) The conditions referred to in sub-paragraph (1) are that -

- (a) the person satisfies the applicable conditions set out in article 3B(3) of the POM Order (prescribing and administration by supplementary prescribers)(a), unless those conditions do not apply by virtue of any of the exemptions set out in the subsequent provisions of that Order;
- (b) the medicine is not a controlled drug within the meaning of the Misuse of Drugs Act 1971;
- (c) the drug, medicine or other substance is not specified in any directions given by the Assembly under section 28U of the Act(b) as being a drug, medicine or other substance which may not be ordered for patients in the provision of medical services under the contract;
- (d) the drug, medicine or other substance is not specified in any directions given by the Assembly under section 28U of the Act as being a drug, medicine or other substance which can only be ordered for specified patients and specified purposes unless -
  - (i) the patient is a person of the specified description,
  - (ii) the medicine is prescribed for that patient only for the specified purposes, and
  - (iii) if the supplementary prescriber is giving a prescription, he or she endorses the face of the form with the reference "SLS".

(3) Where the functions of a supplementary prescriber include prescribing, the contractor shall have arrangements in place to secure that that person will only give a prescription for -

- (a) an appliance; or
- (b) a medicine which is not a prescription only medicine,

as a supplementary prescriber under the conditions set out in sub-paragraph (4).

(4) The conditions referred to in sub-paragraph (3) are that -

- (a) the supplementary prescriber acts in accordance with a clinical management plan which is in effect at the

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(a) Article 3B was inserted into the POM Order by S.I. 2003/696.

(b) The National Health Service (General Medical Services Contracts) (Prescription of Drugs etc) (Wales) Regulations 2004 S.I. 2004/- (W...)



time the supplementary prescriber acts and which contains the following particulars -

- (i) the name of the patient to whom the plan relates,
- (ii) the illness or conditions which may be treated by the supplementary prescriber,
- (iii) the date on which the plan is to take effect, and when it is to be reviewed by the medical practitioner or dentist who is a party to the plan,
- (iv) reference to the class or description of medicines or types of appliances which may be prescribed or administered under the plan,
- (v) any restrictions or limitations as to the strength or dose of any medicine which may be prescribed or administered under the plan, and any period of administration or use of any medicine or appliance which may be prescribed or administered under the plan,
- (vi) relevant warnings about known sensitivities of the patient to, or known difficulties of the patient with, particular medicines or appliances,
- (vii) the arrangements for notification of -
  - (aa) suspected or known adverse reactions to any medicine which may be prescribed or administered under the plan, and suspected or known adverse reactions to any other medicine taken at the same time as any medicine prescribed or administered under the plan,
  - (bb) incidents occurring with the appliance which might lead, might have led or has led to the death or serious deterioration of state of health of the patient, and
- (viii) the circumstances in which the supplementary prescriber should refer to, or seek the advice of, the medical practitioner or dentist who is a party to the plan;
- (b) the supplementary prescriber has access to the health records of the patient to whom the plan relates which are used by any medical practitioner or dentist who is a party to the plan;
- (c) if it is a prescription for a medicine, the medicine is not a controlled drug within the meaning of the Misuse of Drugs Act 1971;
- (d) if it is a prescription for a drug, medicine or other substance, that drug, medicine or other substance is not specified in any directions given by the Assembly under section 28U of the Act<sup>(a)</sup> as being a drug, medicine or other substance which may not be ordered for patients in the provision of medical services under the contract;
- (e) if it is a prescription for a drug, medicine or other substance, that drug, medicine or other substance is not specified in any directions given by the Assembly under section 28U of the Act as being a drug, medicine or other substance which can only be ordered for specified patients and specified purposes unless -
  - (i) the patient is a person of the specified description,
  - (ii) the medicine is prescribed for that patient only for the specified purposes, and
  - (iii) when giving the prescription, the supplementary prescriber endorses the face of the form with the reference "SLS";
- (f) if it is a prescription for a medicine -
  - (i) the medicine is the subject of a product licence, a marketing authorisation or a homeopathic certificate of registration granted by the licensing authority or the European Commission, or
  - (ii) subject to sub-paragraph (6) the use of the medicine is for the purposes of a clinical trial,
    - (aa) that the trial is the subject of a clinical trial certificate issued in accordance with the Medicines Act 1968<sup>(b)</sup>; or
    - (bb) a clinical trial certificate is not needed in respect of that trial by virtue of any exemption conferred by or under that Act;
- (g) if it is a prescription for an appliance, the appliance is listed in Part IX of the Drug Tariff; and
- (h) if it is a prescription for a restricted availability appliance -
  - (i) the patient is a person of a description mentioned in the entry in Part IX of the Drug Tariff in respect of that appliance,
  - (ii) the appliance is prescribed only for the purposes specified in respect of that person in that entry, and
  - (iii) when giving the prescription, the supplementary prescriber endorses the face of the form with the reference SLS.

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(a) insert details of current directions when available.

(b) 1968 c.67.

(5) In sub-paragraph (4)(a), "clinical management plan" means a written plan (which may be amended from time to time) relating to the treatment of an individual patient agreed by

- (a) the patient to whom the plan relates;
- (b) the medical practitioner or dentist who is a party to the plan; and
- (c) any supplementary prescriber who is to prescribe, give directions for administration or administer under the plan.

(6) In relation to any time from the coming into force of any regulations made by the Secretary of State under section 2(2) of the European Communities Act 1972<sup>(a)</sup> to implement Directive 2001/83/EC on the Community Code relating to medicinal products for human use<sup>(b)</sup>, sub-paragraph (4)(f)(ii) shall be read as if it referred to a clinical trial which had been authorised, or is treated as having been authorised by the licensing authority for the purposes of those Regulations.

### **Bulk prescribing**

#### **44.-(1) Where**

- (a) a contractor is responsible under the contract for the treatment of 10 or more persons in a school or other institution in which at least 20 persons normally reside; and
- (b) a prescriber orders, for any two or more of those persons for whose treatment the contractor is responsible, drugs, medicines or appliances to which this paragraph applies,

the prescriber may use a single prescription form for the purpose.

(2) Where a prescriber uses a single prescription form for the purpose mentioned in sub-paragraph (1)(b), the prescriber shall (instead of entering on the form the names of the persons for whom the drugs, medicines or appliances are ordered) enter on the form:

- (a) the name of the school or institution in which those persons reside; and
- (b) the number of persons residing there for whose treatment the contractor is responsible.

(3) This paragraph applies to any drug, medicine or appliance which can be supplied as part of pharmaceutical services or local pharmaceutical services and which-

- (a) in the case of a drug or medicine, is not a product of a description or class which is for the time being specified in an order made under section 58(1) of the Medicines Act 1968 (medicinal products on prescription only)<sup>(c)</sup>; or
- (b) in the case of an appliance, does not contain such a product.

### **Interpretation of paragraphs 38, 39 and 41 to 44**

45. For the purposes of paragraphs 38, 39 and 41 to 44 in their application to a contractor whose contract includes the provision of contraceptive services, drugs includes contraceptive substances and appliances includes contraceptive appliances.

### **Excessive prescribing**

46.-(1) The contractor shall not prescribe drugs, medicines and appliances whose cost or quantity, in relation to any patient, is, by reason of the character of the drug, medicine or appliance in question in excess of that which was reasonably necessary for the proper treatment of that patient.

(2) In considering whether a contractor has breached its obligations under sub-paragraph (1), the Local Health Board shall seek the views of the Local Medical Committee (if any) for its area.

### **Provision of dispensing services**

47.-(1) Without prejudice to any separate right one or more medical practitioners may have under regulation 20 of the Pharmaceutical Regulations, (arrangements for provision of pharmaceutical services by doctors)<sup>(d)</sup> a contractor may secure the provision of dispensing services to its registered patients under the contract only if it is

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- (a) 1972 c.68.
  - (b) OJ L311, 28.11.2001 p.67.
  - (c) 1968 c.67.
  - (d) Regulation 20 was amended by S.I. 1998/681, 1999/696.

authorised or required to do so by the Local Health Board in accordance with the following provisions of this paragraph.

(2) A Local Health Board may authorise or require a contractor to provide dispensing services to a registered patient only if that patient

- (a) satisfies one of the conditions in sub-paragraph (3); and
- (b) has requested the contractor in writing to provide that patient with dispensing services.

(3) The conditions referred to in sub-paragraph (2)(a) are that the patient

- (a) satisfies the Local Health Board that the patient would have serious difficulty in obtaining any necessary drugs, medicines or appliances from a pharmacy by reason of distance or inadequacy of means of communication; or
- (b) is resident in a controlled locality at a distance of more than 1.6 kilometres from any pharmacy, and both the conditions in sub-paragraph (4) are satisfied in the patient's case.

(4) The conditions referred to in sub-paragraph (3)(b) are that

- (a) the contractor has been granted consent to dispense under paragraph 48 in respect of -
  - (i) the area in which the patient resides, and
  - (ii) the contract under which the patient receives primary medical services; and
- (b) any conditions imposed under regulation 12(15) or 13(13)(b) of the Pharmaceutical Regulations as they apply pursuant to paragraph 48(5) or (6) are such as to permit the provision of dispensing services to be provided under this paragraph by that contractor to the patient.

(5) If a contractor has been requested to provide dispensing services by a patient who satisfies one of the conditions in sub-paragraph (3)-

- (a) applies to the Local Health Board for the right to provide dispensing services to that patient, and sends with its application the patient's request to the contractor, the Local Health Board shall grant its application; or
- (b) does not so apply, within the period of 30 days beginning with the date on which the patient made that request, a Local Health Board may, subject to sub-paragraph (7), require the contractor to provide dispensing services to that patient, and shall give the contractor notice in writing to that effect.

(6) An application granted by a Local Health Board under sub-paragraph (5)(a) shall, with effect from the date of the patient's request to the contractor or medical practitioner, enable that contractor to secure the provision of dispensing services to that patient, so long as the contract remains in effect.

(7) A Local Health Board shall not, under sub-paragraph (5)(b), require a contractor to secure the provision of dispensing services to a patient if the contractor satisfies the Local Health Board that -

- (a) it does not normally provide dispensing services under the contract; or
- (b) in the case of a patient to whom sub-paragraph (3)(b) applies, the patient would not have serious difficulty by reason of distance or inadequacy of means of communication in obtaining drugs, medicines or appliances from a pharmacy.

(8) A Local Health Board shall give the contractor reasonable notice -

- (a) that it requires it to provide dispensing services to a registered patient in accordance with the contract; or
- (b) that, subject to sub-paragraph (9), where a patient no longer satisfies the requirements of sub-paragraph (3), the contractor shall discontinue the provision of dispensing services to that patient.

(9) A notice under sub-paragraph (8)(b) -

- (a) shall be subject to any postponement or termination of arrangements to provide dispensing services under this paragraph in accordance with conditions imposed under regulation 12(15) or 13(13) of the Pharmaceutical Regulations as they apply pursuant to paragraph 48(5) or (6); and -
- (b) shall not be given -
  - (i) pending the outcome of the resolution of any dispute concerning the decision by a Local Health Board to postpone the making or termination of arrangements to provide dispensing services under this paragraph in accordance with conditions referred to in paragraph (a); or
  - (ii) during the period for bringing an appeal, or pending the determination of any appeal, referred to in regulation 9(10) of the Pharmaceutical Regulations (determination of whether an area is a controlled locality).

(10) A contractor which has been granted the right under this paragraph to provide dispensing services to some or all of its registered patients may provide any necessary dispensing services to a person whom that contractor has accepted as a temporary resident.

(11) In this paragraph, "controlled locality" and "pharmacy" have the same meanings as in the Pharmaceutical Regulations.

### **Consent to dispense**

**48.**-(1) A contractor which wishes to be granted the right under paragraph 47 to secure the provision of dispensing services to some or all of its registered patients may apply to the Local Health Board in writing for consent to dispense, specifying -

- (a) the area; and
- (b) the contract,

in relation to which it wishes the consent to dispense to be granted.

(2) An application under sub-paragraph (1) shall be determined by the Local Health Board in accordance with regulations 12 and 13 of the Pharmaceutical Regulations (as modified in accordance with sub-paragraphs (5) and (6)), as though it were an application under regulation 21 of those Regulations.

(3) Consent to dispense, in relation to the specified contract, shall have effect from its final grant but shall cease to have effect if -

- (a) no dispensing services have been provided under that contract within 12 months from the final grant of the consent to dispense; or
- (b) more than 12 months has elapsed since the last provision of dispensing services under that contract pursuant to the grant of consent.

(4) In sub-paragraph (3), "final grant" shall be construed in accordance with regulation 12(16) of the Pharmaceutical Regulations.

(5) Regulation 12 of the Pharmaceutical Regulations shall apply as if modified as follows -

- (a) all references to provisions being "subject to regulation 6A" were omitted;
- (b) for all references to regulation 21, there were substituted references to this paragraph; and
- (c) in paragraph (14), the reference to "regulation 4(4)" were omitted; and
- (d) in paragraph (15), for "regulation 20" there were substituted a reference to paragraph 47, and for the reference to "provision by a doctor of pharmaceutical services" there were substituted a reference to dispensing services.

(6) Regulation 13 of the Pharmaceutical Regulations shall apply as if modified as follows -

- (a) in paragraph (2), for "regulation 20" there were substituted a reference to paragraph 47; and
- (b) in paragraph (13)(b), for "regulation 20" there were substituted a reference to paragraph 47, and for the reference to "provision by a doctor of pharmaceutical services" there were substituted a reference to dispensing services.

### **Terms relating to the provision of dispensing services**

**49.**-(1) A contractor which has been granted the right to provide dispensing services under paragraph 47 shall ensure that dispensing services are provided in accordance with the following sub-paragraphs.

(2) Subject to sub-paragraphs (3) and (4), a contractor providing dispensing services shall -

- (a) record an order for the provision of any drugs, medicines or appliances which are needed for the treatment of the patient on a prescription form completed in accordance with paragraph 39(3);
- (b) provide those drugs, medicines or appliances in a suitable container;
- (c) provide for the patient a drug or medicine specified in any directions given by the Assembly under section 28U of the Act (GMS contracts : prescription of drugs etc)(a) as being a drug or medicine which can only be ordered for specified patients and specified purposes only if -
  - (i) that patient is a person of the specified description, and

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(a) The National Health Service (General Medical Services Contracts) (Prescription of Drugs etc) (Wales) Regulations 2004 S.I. 2004/.... (W....).

- (ii) the drug or medicine is supplied for that patient only for the specified purpose; and
- (d) provide for the patient a restricted availability appliance only if the patient is a person, or it is for a purpose, specified in the Drug Tariff.

(3) Sub-paragraph (2) does not apply to drugs, medicines or appliances ordered on a prescription form by an independent nurse prescriber.

(4) Where a patient presents an order on a prescription form for drugs, medicines or appliances signed by an independent nurse prescriber, or an order for a restricted availability appliance signed by and endorsed on its face with the reference "SLS" by an independent nurse prescriber, to a contractor who may provide dispensing services, the contractor may provide to the patient such of the drugs, medicines or appliances so ordered as it supplies in the normal course of its practice.

(5) Drugs, medicines or appliances provided under sub-paragraph (4) shall be provided in a suitable container.

(6) A contractor providing dispensing services shall not provide for a patient a drug or medicine specified in any directions given by the Assembly under section 28U of the Act as being drugs or medicines which may not be ordered for patients in the provision of medical services under the contract, except that, where it has ordered a drug or medicine which has an appropriate non-proprietary name either by the name or by its formula, it may provide a drug or medicine which has the same specification notwithstanding that it is a drug or medicine specified in such directions (but, in the case of a drug or medicine which combines more than one drug, only if the combination has an appropriate non-proprietary name).

(7) Subject to sub-paragraph (10), nothing in this paragraph shall prevent the contractor providing a Scheduled drug or a restricted availability appliance in the course of treating a patient under a private arrangement.

(8) A contractor providing dispensing services shall comply with paragraph 11B of Schedule 2 to the Pharmaceutical Regulations, as if modified as follows -

- (a) for "paragraph 11(a)", substitute "sub-paragraph (2)(a)";
- (b) for "paragraph 11A(2)", substitute "sub-paragraph (5)";
- (c) for "a doctor who is authorised or required by the Health Authority or Primary Care Trust under regulation 20 to provide drugs and appliances to a patient", substitute "a contractor providing dispensing services to a patient"; and
- (d) for "doctor", substitute "medical practitioner".

(9) The provisions of regulation 24 (fees and charges) apply in respect of the provision of any drugs, medicines or appliances by a contractor providing dispensing services as they apply in respect of prescriptions for drugs, medicines or appliances.

(10) A contractor who is entitled to provide dispensing services may, with the consent of the patient, order a drug, medicine or appliance for a patient on a prescription form or a repeatable prescription, rather than providing it itself.

### **Dispensing contractor list**

**50.**-(1) Where the contractor is authorised or required by the Local Health Board under paragraph 47 to provide dispensing services to its patients and is actually doing so, the Local Health Board shall include -

- (a) the contractor's name; and
- (b) the address of the practice premises from which it is authorised or required to dispense,

on a list of such contractors (to be called the dispensing contractors list) which it shall prepare, maintain and publish.

(2) The Local Health Board shall remove the name of the contractor from the list referred to in sub-paragraph (1) where -

- (a) the contractor's consent to dispense ceases to have effect pursuant to paragraph 48(3); or
- (b) the contractor ceases to provide dispensing services to its patients for any other reason.

## **Provision of drugs, medicines and appliances for immediate treatment or personal administration**

**51.**-(1) Subject to sub-paragraph (2), a contractor -

- (a) shall provide to a patient any drug, medicine or appliance, not being a Scheduled drug, where such provision is needed for the immediate treatment of that patient before a provision can otherwise be obtained; and
- (b) may provide to a patient any drug, medicine or appliance, not being a Scheduled drug, which the contractor personally administers or applies to that patient,

but shall, in either case, provide a restricted availability appliance only if it is for a person or a purpose specified in the Drug Tariff.

(2) Nothing in sub-paragraph (1) authorises a person to supply any drug or medicine to a patient otherwise than in accordance with the Medicines Act 1968(a) or any regulations or orders made thereunder.

## **PART 4**

### **PERSONS WHO PERFORM SERVICES**

#### **Qualifications of performers**

**52.**-(1) Subject to sub-paragraph (2), no medical practitioner shall perform medical services under the contract unless the medical practitioner is

- (a) included in a medical performers' list for a Local Health Board in Wales;
- (b) not suspended from that list or from the Medical Register; and
- (c) not subject to interim suspension under section 41A of the Medical Act 1983 (interim order)(b).

(2) Sub-paragraph (1)(a) shall not apply in the case of

- (a) a medical practitioner employed by an NHS trust, an NHS foundation trust, (in Scotland) a Health Board, or (in Northern Ireland) a Health and Social Services Trust who is providing services other than primary medical services at the practice premises;
- (b) a person who is provisionally registered under section 15 (provisional registration), 15A (provisional registration for EEA nationals) or 21 (provisional registration) of the Medical Act 1983(c) acting in the course of the person's employment in a resident medical capacity in an approved medical practice; or
- (c) a GP Registrar during the first two months of his or her training period.

**53.** No health care professional other than one to which paragraph 52 applies shall perform clinical services under the contract unless that health care professional is appropriately registered with the health care professional's relevant professional body and the health care professional's registration is not currently suspended.

**54.** Where the registration of a health care professional or, in the case of a medical practitioner, the medical practitioner's inclusion in a primary care list is subject to conditions, the contractor shall ensure compliance with those conditions insofar as they are relevant to the contract.

**55.**- No health care professional shall perform any clinical services unless the health care professional has such clinical experience and training as are necessary to enable the health care professional properly to perform such services.

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(a) Paragraph 11B was inserted by S.I. 1999/696 and amended by S.I. 1999/2563; 2001/28881 2002/551 and 2469, 2003/999 and 1084.

(b) 1983 c.54. Section 41 was inserted by S.I. 2000/1803.

(c) 1983 c. 54. Section 15A was inserted by regulations 2 and 3 of S.I. 2000/3041.

## **Conditions for employment and engagement**

**56.**-(1) Subject to sub-paragraphs (2) and (3), a contractor shall not employ or engage a medical practitioner (other than one falling within paragraph 52(2)) unless-

- (a) that practitioner has provided it with the name and address of the Local Health Board on whose medical performers list the practitioner appears; and
- (b) the contractor has checked that the practitioner meets the requirements in paragraph 52.

(2) Where the employment or engagement of a medical practitioner is urgently needed and it is not possible for the contractor to check the matters referred to in paragraph 52 in accordance with sub-paragraph (1)(b) before employing or engaging the medical practitioner, the medical practitioner may be employed or engaged on a temporary basis for a single period of up to 7 days whilst such checks are undertaken.

(3) Where the prospective employee is a GP Registrar, the requirements set out in sub-paragraph (1) shall apply with the modifications that -

- (a) the name and address provided under sub-paragraph (1) may be the name and address of the Local Health Board on whose list the GP Registrar has applied for inclusion; and
- (b) confirmation that GP Registrar's name appears on that list shall not be required until the end of the first two months of the GP Registrar's training period.

**57.**-(1) A contractor shall not employ or engage -

- (a) a health care professional other than one to whom paragraph 52 applies unless the contractor has checked that the health care professional meets the requirements in paragraph 53; or
- (b) a health care professional to perform clinical services unless the contractor has taken reasonable steps to satisfy itself that the health care professional meets the requirements in paragraph 55.

(2) Where the employment or engagement of a health care professional is urgently needed and it is not possible to check the matters referred to in paragraph 53 in accordance with sub-paragraph (1) before employing or engaging the health care professional, the health care professional may be employed or engaged on a temporary basis for a single period of up to 7 days whilst such checks are undertaken.

(3) When considering a health care professional's experience and training for the purpose of sub-paragraph (1)(b), the contractor shall have regard in particular to -

- (a) any post-graduate or post-registration qualification held by the health care professional; and
- (b) any relevant training undertaken by the health care professional and any relevant clinical experience gained by the health care professional.

**58.**-(1) The contractor shall not employ or engage a health care professional to perform medical services under the contract unless -

- (a) that person has provided two clinical references, relating to two recent posts (which may include any current post) as a health care professional which lasted for three months without a significant break, or where this is not possible, a full explanation and alternative referees; and
- (b) the contractor has checked and is satisfied with the references.

(2) Where the employment or engagement of a health care professional is urgently needed and it is not possible to obtain and check the references in accordance with sub-paragraph (1)(b) before employing or engaging the health care professional, the health care professional may be employed or engaged on a temporary basis for a single period of up to 14 days whilst the health care professional's references are checked and considered, and for an additional single period of a further 7 days if the contractor believes the person supplying those references is ill, on holiday or otherwise temporarily unavailable.

(3) Where the contractor employs or engages the same person on more than one occasion within a period of three months, it may rely on the references provided on the first occasion, provided that those references are not more than twelve months old.

**59.**-(1) Before employing or engaging any person to assist it in the provision of services under the contract, the contractor shall take reasonable care to satisfy itself that the person in question is both suitably qualified and competent to discharge the duties for which that person is to be employed or engaged.

(2) The duty imposed by sub-paragraph (1) is in addition to the duties imposed by paragraphs 56 to 58.

(3) When considering the competence and suitability of any person for the purpose of sub-paragraph (1), the

contractor shall have regard, in particular, to -

- (a) that person's academic and vocational qualifications;
- (b) that person's education and training; and
- (c) that person's previous employment or work experience.

### **Training**

**60.** The contractor shall ensure that for any health care professional who is -

- (a) performing clinical services under the contract; or
- (b) employed or engaged to assist in the performance of such services,

there are in place arrangements for the purpose of maintaining and updating the health care professional's skills and knowledge in relation to the services which he or she is performing or assisting in performing.

**61.** The contractor shall afford to each employee reasonable opportunities to undertake appropriate training with a view to maintaining that employee's competence.

### **Terms and conditions**

**62.** The contractor shall only offer employment to a general medical practitioner on terms and conditions which are no less favourable than those contained in the "Model terms and conditions of service for a salaried general practitioner employed by a GMS practice" published by the British Medical Association and the NHS Confederation as item 1.2 of the supplementary documents to the new GMS contract 2003(a).

### **Arrangements for GP Registrars**

**63.**-(1) The contractor shall only employ a GP Registrar for the purpose of being trained by a GP Trainer with the agreement of the Assembly and subject to the conditions in sub-paragraph (2).

(2) The conditions referred to in sub-paragraph (1) are that the contractor shall not, by reason only of having employed or engaged a GP Registrar, reduce the total number of hours for which other medical practitioners perform primary medical services under the contract or for which other staff assist them in the performance of those services.

(3) A contractor which employs a GP Registrar shall -

- (a) offer the GP Registrar terms of employment in accordance with the rates and subject to the conditions contained in any directions given by the Assembly to Local Health Boards under section 16BB(4) of the Act (Assembly's directions : exercise of functions) concerning the grants, fees travelling and other allowances payable to GP Registrars (b); and
- (b) take into account any guidance issued by the Assembly in relation to the GP Registrar Scheme(c).

### **Independent nurse prescribers and supplementary prescribers**

**64.**-(1) Where -

- (a) a contractor employs or engages a person who is an independent nurse prescriber or a supplementary prescriber whose functions will include prescribing;
- (b) a party to the contract is an independent nurse prescriber or a supplementary prescriber whose functions will include prescribing; or

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(a) This document is published jointly by the General Practitioners Committee of the British Medical Association and the NHS Confederation. A copy may be obtained by writing to the NHS Confederation, 1 Warwick Row, London SW1E 5ER.

(b) The current directions are the Directions to Local Health Boards concerning the GP Vocational Training Scheme (GPTVS) dated December 2003.. A copy of these directions can be found on the Assembly's website at [www.wales.gov.uk/subihealth](http://www.wales.gov.uk/subihealth) or a copy may be obtained by writing to **Education, Training and Development Branch, NHS HR Division National Assembly for Wales, Cathays Park, Cardiff CF10 3NQ.**

(c) The current guidance is the GP Registrar Scheme Vocational Guide for General Medical Practice - the UK Guide 2000 published by the Department of Health and available on their website at [www.doh.gov.uk/medicaltrainingintheuk](http://www.doh.gov.uk/medicaltrainingintheuk).



- (c) the functions of a person who is an independent nurse prescriber or a supplementary prescriber whom the contractor already employs or has already engaged are extended to include prescribing,

it shall notify the Local Health Board in writing within the period of seven days beginning with the date on which the contractor employed or engaged the person, the party became a party to the contract (unless, immediately before becoming such a party, the person fell under paragraph (1)(a)) or the person's functions were extended, as the case may be.

(2) Where -

- (a) the contractor ceases to employ or engage a person who is an independent nurse prescriber or a supplementary prescriber whose functions included prescribing in its practice;
- (b) a party to the contract is an independent nurse prescriber or a supplementary prescriber whose functions will include prescribing, ceases to be a party to the contract;
- (c) the functions of a person who is an independent nurse prescriber or a supplementary prescriber whom the contractor employs or engages in its practice are changed so that they no longer include prescribing in its practice; or
- (d) the contractor becomes aware that a person who is an independent nurse prescriber or a supplementary prescriber whom it employs or engages has been removed or suspended from the relevant register,

it shall notify the Local Health Board in writing by the end of the second working day after the day when the event occurred.

(3) The contractor shall provide the following information when it notifies the Local Health Board in accordance with sub-paragraph (1) -

- (a) the person's full name;
- (b) the person's professional qualifications;
- (c) the person's identifying number which appears in the relevant register;
- (d) the date on which the person's entry in the relevant register was annotated to the effect that the person was qualified to order drugs, medicines and appliances for patients;
- (e) the date on which -
  - (i) the person was employed or engaged, if applicable,
  - (ii) the person became a party to the contract if applicable, or
  - (iii) one of the person's functions became to prescribe in its practice.

(4) The contractor shall provide the following information when it notifies the Local Health Board in accordance with sub-paragraph (2) -

- (a) the person's full name;
- (b) the person's professional qualifications;
- (c) the person's identifying number which appears in the relevant register;
- (d) the date -
  - (i) the person ceased to be employed or engaged in its practice,
  - (ii) the person ceased to be a party to the contract,
  - (iii) the person's functions changed so as no longer to include prescribing, or
  - (iv) on which the person was removed or suspended from the relevant register.

### **Signing of documents**

65.-(1) In addition to any other requirements relating to such documents whether in these regulations or otherwise, the contractor shall ensure that the documents specified in paragraph (2) include -

- (a) the clinical profession of the health care professional who signed the document; and
- (b) the name of the contractor on whose behalf it is signed.

(2) The documents referred to in sub-paragraph (1) are

- (a) certificates issued in accordance with regulation 21, unless regulations relating to particular certificates provide otherwise;

- (b) prescription forms and repeatable prescriptions; and
- (c) any other clinical documents.

### **Level of skill**

66. The contractor shall carry out its obligations under the contract with reasonable care and skill.

### **Appraisal and assessment**

67.-(1) The contractor shall ensure that any medical practitioner performing services under the contract -

- (a) participates in the appraisal system provided on behalf of the Local Health Board unless the medical practitioner is an armed forces GP; and
- (b) co-operates with an assessment by the NCAA when requested to do so by the Local Health Board.

(2) In sub-paragraph (1), "armed forces GP" means a medical practitioner who is employed on a contract of service by the Ministry of Defence, whether or not as a member of the United Kingdom Armed Forces of Her Majesty.

### **Sub-contracting of clinical matters**

68.-(1) Subject to sub-paragraph (2), the contractor shall not sub-contract any of its rights or duties under the contract in relation to clinical matters unless -

- (a) in all cases, including those which fall within paragraph 69, it has taken reasonable steps to satisfy itself that -
  - (i) it is reasonable in all the circumstances; and
  - (ii) that person is qualified and competent to provide the service; and
- (b) except in cases which fall within paragraph 69, it has notified the Local Health Board of its intention to sub-contract as soon as reasonably practicable before the date on which the proposed sub-contract is intended to come into force.

(2) Sub-paragraph (1)(b) shall not apply to a contract for services with a health care professional for the provision by that professional personally of clinical services.

(3) The notification referred to in sub-paragraph (1)(b) shall include -

- (a) the name and address of the proposed sub-contractor;
- (b) the duration of the proposed sub-contract;
- (c) the services to be covered; and
- (d) the address of any premises to be used for the provision of services.

(4) Following receipt of a notice in accordance with sub-paragraph (1)(b), the Local Health Board may request such further information relating to the proposed sub-contract as appears to it to be reasonable and the contractor shall supply such information promptly.

(5) The contractor shall not proceed with the sub-contract or, if it has already taken effect, shall take appropriate steps to terminate it, where, within 28 days of receipt of the notice referred to in sub-paragraph (1)(b), the Local Health Board has served notice of objection to the sub-contract on the grounds that

- (a) the sub-contract would -
  - (i) put at serious risk the safety of the contractor's patients, or
  - (ii) put the Local Health Board at risk of material financial loss; or
- (b) the sub-contractor would be unable to meet the contractor's obligations under the contract.

(6) Where the Local Health Board objects to a proposed sub-contract in accordance with sub-paragraph (5), it shall include with the notice of objection a statement in writing of the reasons for its objection.

(7) Sub-paragraphs (1) and (3) to (6) shall also apply in relation to any renewal or material variation of a sub-contract in relation to clinical matters.

(8) Where a Local Health Board does not object to a proposed sub-contract under paragraph (5), the parties to

the contract shall be deemed to have agreed a variation of the contract which has the effect of adding to the list of practice premises any premises whose address was notified to it under sub-paragraph (3)(d) and paragraph 102(1) shall not apply.

(9) A contract with a sub-contractor must prohibit the sub-contractor from sub-contracting the clinical services it has agreed with the contractor to provide.

### **Sub-contracting of out of hours services**

**69.**-(1) A contractor shall not, otherwise than in accordance with the written approval of the Local Health Board, sub-contract all or part of its duty to provide out of hours services to any person other than those listed in sub-paragraph (2) other than on a short-term occasional basis.

(2) The persons referred to in sub-paragraph (1) are-

- (a) a person who holds a general medical services contract with a Local Health Board which includes out of hours services;
- (b) a section 28C provider who is required to provide the equivalent of essential services to his patients during all or part of the out of hours period;
- (c) a health care professional, not falling within paragraph (a) or (b), who is to provide the out of hours services personally under a contract for services; or

a group of medical practitioners, whether in partnership or not, who provide out of hours services for each other under informal rota arrangements.

(3) An application for approval under sub-paragraph (1) shall be made by the contractor in writing to the Local Health Board and shall state -

- (a) the name and address of the proposed sub-contractor;
- (b) the address of any premises used for the provision of services;
- (c) the duration of the proposed sub-contract;
- (d) the services to be covered by the arrangement; and
- (e) how it is proposed that the sub-contractor will meet the contractor's obligations under the contract in respect of the services covered by the arrangement.

(4) Within 7 days of receipt of an application under sub-paragraph (3), a Local Health Board may request such further information relating to the proposed arrangements as seem to it to be reasonable.

(5) Within 28 days of receipt of an application which meets the requirements specified in sub-paragraph (3) or the further information requested under sub-paragraph (4) (whichever is the later), the Local Health Board shall

- (a) approve the application;
- (b) approve the application with conditions; or
- (c) refuse the application.

(6) The Local Health Board shall approve the application (with or without conditions) if it is satisfied that the proposed arrangement will, in respect of the services to be covered, enable the contractor to meet satisfactorily its obligations under the contract and will not-

- (a) put at serious risk the safety of the contractor's patients; or
- (b) put the Local Health Board at risk of material financial loss.

(7) The Local Health Board shall inform the contractor by notice in writing of its decision on the application and, where it refuses an application, it shall include in the notice a statement of the reasons for its refusal.

(8) Where a Local Health Board approves an application under this paragraph the parties to the contract shall be deemed to have agreed a variation of the contract which has the effect of adding to the list of practice premises any premises, for the purposes of the provision of services in accordance with that application whose address was notified to it under sub-paragraph (3)(b) and paragraph 102(1) shall not apply.

(9) Sub-paragraphs (1) to (8) shall also apply in relation to any renewal or material variation of a sub-contract in relation to out of hours services .

(10) A contract with a sub-contractor must prohibit the sub-contractor from sub-contracting the out of hours

services it has agreed with the contractor to provide.

### **Withdrawal and variation of approval under paragraph 69**

**70.**-(1) Without prejudice to any other remedies which it may have under the contract, where a Local Health Board has approved an application made under paragraph 69(3) it shall, subject to paragraph 71, be entitled to serve notice on the contractor withdrawing or varying that approval, from a date specified in the notice, if it is no longer satisfied that the proposed arrangement will enable the contractor to meet satisfactorily its obligations under the contract.

(2) The date specified in the notice shall be such as appears reasonable in all the circumstances to the Local Health Board.

(3) The notice referred to in sub-paragraph (1) shall take effect on whichever is the later of -

- (a) the date specified in the notice; or
- (b) (if applicable) the date of the final determination of the NHS dispute resolution procedure (or any court proceedings) relating to the notice in favour of the Local Health Board.

**71.**-(1) Without prejudice to any other remedies which it may have under the contract, where a Local Health Board has approved an application made under paragraph 69(3) it shall be entitled to serve notice on the contractor withdrawing or varying that approval with immediate effect if -

- (a) it is no longer satisfied that the proposed arrangement will enable the contractor to meet satisfactorily its obligations under the contract.; and
- (b) it is satisfied that immediate withdrawal or variation is necessary to protect the safety of the contractor's patients.

(2) An immediate withdrawal of approval under sub-paragraph (1) shall take effect on the date on which the notice referred to in that sub-paragraph is received by the contractor.

## **PART 5**

### **RECORDS, INFORMATION, NOTIFICATIONS AND RIGHTS OF ENTRY**

#### **Patient records**

**72.**-(1) In this paragraph, "computerised records" means records created by way of entries on a computer.

(2) The contractor shall keep adequate records of its attendance on and treatment of its patients and shall do so -

- (a) on forms supplied to it for the purpose by the Local Health Board; or
- (b) with the written consent of the Local Health Board, by way of computerised records,

or in a combination of those two ways.

(3) The contractor shall include in the records referred to in sub-paragraph (2) clinical reports sent in accordance with paragraph 7 of this Schedule or from any other health care professional who has provided clinical services to a person on its list of patients.

(4) The consent of the Local Health Board required by sub-paragraph (2)(b) shall not be withheld or withdrawn provided the Local Health Board is satisfied, and continues to be satisfied, that -

- (a) the computer system upon which the contractor proposes to keep the records has been accredited by the Assembly or another person on its behalf in accordance with "General Medical Practice Computer Systems- Requirements for Accreditation - RFA99 version 1.0, 1.1 or 1.2 (DTS/Nurse Prescribing)(a);

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(a) RFA99 is published by the NHS Information Authority. Version 1.0 was published in October 1999, version 1.1 in February 2001 and version 1.2 (DTS/Nurse Prescribing) in August 2003. Copies may be obtained by writing to the Authority, RFA team, Aqueous 2, Aston Cross, Rocky Lane, Birmingham B6 5RQ.

- (b) the security measures, audit and system management functions incorporated into the computer system as accredited in accordance with paragraph (a) have been enabled; and
- (c) the contractor is aware of, and has signed an undertaking that it will have regard to the guidelines contained in "Good Practice Guidelines for General Practice Electronic Patient Records" published on 26th September 2003(a).

(5) Where a patient's records are computerised records, the contractor shall, as soon as possible following a request from the Local Health Board, allow the Local Health Board to access the information recorded on the computer system on which those records are held by means of the audit function referred to in sub-paragraph (4)(b) to the extent necessary for the Local Health Board to confirm that the audit function is enabled and functioning correctly.

(6) The contractor shall send the complete records relating to a patient to the Local Health Board -

- (a) where a person on its list dies, before the end of the period of 14 days beginning with the date on which it was informed by the Local Health Board of the death, or (in any other case) before the end of the period of one month beginning with the date on which it learned of the death;
- (b) In any other case where the person is no longer registered with the contractor, as soon as possible at the request of the Local Health Board.

(7) To the extent that a patient's records are computerised records, the contractor complies with sub-paragraph (6) if it sends to the Local Health Board a copy of those records -

- (a) in written form; or
- (b) with the written consent of the Local Health Board in any other form.

(8) The consent of the Local Health Board to the transmission of information other than in written form for the purposes of sub-paragraph (7)(b) shall not be withheld or withdrawn provided it is satisfied, and continues to be satisfied, with the following matters -

- (a) the contractor's proposals as to how the record will be transmitted;
- (b) the contractor's proposals as to the format of the transmitted record;
- (c) how the contractor will ensure that the record received by the Local Health Board is identical to that transmitted; and
- (d) how a written copy of the record can be produced by the Local Health Board.

(9) A contractor whose patient records are computerised records shall not disable, or attempt to disable, either the security measures or the audit and system management functions referred to in sub-paragraph (4)(b).

### **Access to records for the purpose of the Quality Information Preparation Scheme**

73.-(1) The contractor must provide access to its patient records on request to any appropriately qualified person with whom the Local Health Board has made arrangements for the provision of the information preparation scheme referred to in section 7 of the GMS Statement of Financial Entitlements.

(2) The contractor shall not be obliged to grant access to a person referred to in sub-paragraph (1) unless he or she produces, on request, written evidence that the person is authorised by the Local Health Board to act on its behalf.

### **Confidentiality of personal data**

74. The contractor shall nominate a person with responsibility for practices and procedures relating to the confidentiality of personal data held by it.

### **Practice leaflet**

75. The contractor shall -

- (a) compile a document (in this paragraph called a practice leaflet) which shall include the information specified in Schedule 10;
- (b) review its practice leaflet at least once in every period of 12 months and make any amendments necessary

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(a) This document is available on the Department of Health website at [www.doh.gov.uk/pricare/computing](http://www.doh.gov.uk/pricare/computing) or a copy can be obtained by writing to the Department of Health, PCIT Branch, Room 1N06, Quarry House, Quarry Hill, Leeds LS2 7UE. .

to maintain its accuracy; and

- (c) make available a copy of the leaflet, and any subsequent updates, to its patients and prospective patients.

### **Provision of information**

76. Subject to sub-paragraph (2), the contractor shall, at the request of the Local Health Board, produce to the Local Health Board or to a person authorised in writing by the Local Health Board or allow it, or a person authorised in writing by it, to access-

- (a) any information which is reasonably required by the Local Health Board for the purposes of or in connection with the contract; and
- (b) any other information which is reasonably required in connection with the Local Health Board functions.

(2) The contractor shall not be required to comply with any request made in accordance with sub-paragraph (1) unless it has been made by the Local Health Board in accordance with directions relating to the provision of information by contractors given to it by the Assembly under section 16BB(4) of the Act.

### **Inquiries about prescriptions and referrals**

77.-(1) The contractor shall, subject to sub-paragraphs (2) and (3), sufficiently answer any inquiries whether oral or in writing from the Local Health Board concerning -

- (a) any prescription form or repeatable prescription issued by a prescriber ;
- (b) the considerations by reference to which prescribers by it issue such forms;
- (c) the referral by or on behalf of the contractor of any patient to any other services provided under the Act; or
- (d) the considerations by which the contractor makes such referrals or provides for them to be made on its behalf.

(2) An inquiry referred to in sub-paragraph (1) may only be made for the purpose either of obtaining information to assist the Local Health Board to discharge its functions or of assisting the contractor in the discharge of its obligations under the contract.

(3) The contractor shall not be obliged to answer any inquiry referred to in sub-paragraph (1) unless it is made -

- (a) in the case of sub-paragraph (1)(a) or (b), by an appropriately qualified health care professional; or
- (b) in the case of sub-paragraph (1)(c) or (d), by an appropriately qualified medical practitioner,

appointed in either case by the Local Health Board to assist it in the exercise of its functions under this paragraph and the health care professional or medical practitioner produces, on request, written evidence that the health care professional or medical practitioner is authorised by the Local Health Board to make such an inquiry on its behalf.

### **Reports to a medical officer**

78.-(1) The contractor shall, if it is satisfied that the patient consents -

- (a) supply in writing to a medical officer within such reasonable period as that officer, or an officer of the Department for Work and Pensions on the medical officer's behalf and at the officer's direction, may specify, such clinical information as the medical officer considers relevant about a patient to whom the contractor or a person acting on the contractor's behalf has issued or has refused to issue a medical certificate; and
- (b) answer any inquiries by a medical officer, or by an officer of the Department for Work and Pensions on the officer's behalf and at the officer's direction, about a prescription form or medical certificate issued by the contractor or on its behalf or about any statement which the contractor or a person acting on the contractor's behalf has made in a report.

(2) For the purpose of satisfying itself that the patient has consented as required by paragraph (1), the contractor may (unless it has reason to believe the patient does not consent) rely on an assurance in writing from the medical officer, or any officer of the Department for Work and Pensions, that medical officer or officer of the Department for Work and Pensions holds the patient's written consent.

## **Annual return and review**

79.-(1) The contractor shall submit an annual return relating to the contract to the Local Health Board which shall require the same categories of information from all persons who hold contracts with that Local Health Board.

(2) Following receipt of the return referred to in sub-paragraph (1), the Local Health Board shall arrange with the contractor an annual review of its performance in relation to the contract.

(3) Either the contractor or the Local Health Board may, if it wishes to do so, invite the Local Medical Committee for the area of the Local Health Board to participate in the annual review.

(4) The Local Health Board shall prepare a draft record of the review referred to in sub-paragraph (2) for comment by the contractor and, having regard to such comments, shall produce a final written record of the review.

(5) A copy of the final record referred to in sub-paragraph (4) shall be sent to the contractor.

## **Notifications to the Local Health Board**

80. In addition to any requirements of notification elsewhere in the regulations, the contractor shall notify the Local Health Board in writing, as soon as reasonably practicable, of -

- (a) any serious incident that, in the reasonable opinion of the contractor, affects or is likely to affect the contractor's performance of its obligations under the contract;
- (b) any circumstances which give rise to the Local Health Board's right to terminate the contract under paragraph 109, 110 or 111(1);
- (c) any appointments system which it proposes to operate and the proposed discontinuance of any such system;
- (d) any change of which it is aware in the address of a registered patient; and
- (e) the death of any patient of which it is aware.

81. The contractor shall, unless it is impracticable for it to do so, notify the Local Health Board in writing within 28 days of any occurrence requiring a change in the information about it published by the Local Health Board in accordance with regulations made under section 16CC(3) of the Act (primary medical services)(a).

82. The contractor shall notify the Local Health Board in writing of any person other than a registered patient or a person whom it has accepted as a temporary resident to whom it has provided the essential services described in regulation 15(6) or (8) within the period of 28 days beginning on the day that the services were provided.

## **Notice provisions specific to a contract with a company limited by shares**

83.-(1) A contractor which is a company limited by shares shall give notice in writing to the Local Health Board forthwith when  $\frac{3}{4}$

- (a) any share in the contractor is transmitted or transferred (whether legally or beneficially) to another person on a date after the contract has been entered into;
- (b) it passes a resolution or a court of competent jurisdiction makes an order that the contractor be wound up;
- (c) circumstances arise which might entitle a creditor or a court to appoint a receiver, administrator or administrative receiver for the contractor;
- (d) circumstances arise which would enable the court to make a winding up order in respect of the contractor ; or
- (e) the contractor is unable to pay its debts within the meaning of section 123 of the Insolvency Act 1986 (definition of inability to pay debts)(b).

(2) A notice under sub-paragraph (1)(a) shall confirm that the new shareholder, or, as the case may be, the personal representative of a deceased shareholder -

- (a) is a medical practitioner, or that he or she satisfies the conditions specified in section 28S(2)(b)(i) to (iv) of the Act; and
- (b) meets the further conditions imposed on shareholders by virtue of regulations 4 and 5.

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(a) Section 16CC was inserted into the Act by section 170 of the 2003 Act. The current regulations are.....

(b) 1986 c.45.

### **Notice provisions specific to a contract with two or more individuals practising in partnership**

**84.**-(1) A contractor which is a partnership shall give notice in writing to the Local Health Board forthwith when -

- (a) a partner leaves or informs his or her partners that he or she intends to leave the partnership, and the date upon which he or she left or will leave the partnership;
- (b) a new partner joins the partnership;

(2) A notice under sub-paragraph (1)(b) shall -

- (a) state the date that the new partner joined the partnership;
- (b) confirm that the new partner is a medical practitioner, or that the new partner satisfies the conditions specified in section 28S(2)(b)(i) to (iv) of the Act ;
- (c) confirm that the new partner meets the conditions imposed by regulations 4 and 5; and
- (d) state whether the new partner is a general or a limited partner.

### **Notification of deaths**

**85.**-(1) The contractor shall report in writing to the Local Health Board the death on its practice premises of any patient no later than the end of the first working day after the date on which the death occurred.

(2) The report shall include -

- (a) the patient's full name;
- (b) the patient's National Health Service number where known;
- (c) the date and place of death;
- (d) a brief description of the circumstances, as known, surrounding the death;
- (e) the name of any medical practitioner or other person treating the patient whilst on the practice premises; and
- (f) the name, where known, of any other person who was present at the time of the death.

(3) The contractor shall send a copy of the report referred to in sub-paragraph (1) to any other Local Health Board in whose area the deceased was resident at the time of the deceased's death.

### **Notifications to patients following variation of the contract**

**86.** Where the contract is varied in accordance with Part 8 of this Schedule and, as a result of that variation -

- (a) there is to be a change in the range of services provided to the contractor's registered patients; or
- (b) patients who are on the contractor's list of patients are to be removed from that list;

the Local Health Board shall notify those patients in writing of the variation and its effect and inform them of the steps they can take to obtain elsewhere the services in question or, as the case may be, register elsewhere for the provision of essential services(or their equivalent).

### **Entry and Inspection by the Local Health Board**

**87.**-(1) Subject to the conditions in sub-paragraph (2), the contractor shall allow persons authorised in writing by the Local Health Board to enter and inspect the practice premises at any reasonable time.

(2) The conditions referred to in sub-paragraph (1) are that -

- (a) reasonable notice of the intended entry has been given;
- (b) written evidence of the authority of the person seeking entry is produced to the contractor on request; and
- (c) entry is not made to any premises or part of the premises used as residential accommodation without the consent of the resident.

(3) Either the contractor or the Local Health Board may, if it so wishes to do so, invite the Local Medical Committee (if any) for the area of the Local Health Board to be present at an inspection of the practice premises which takes place under this paragraph.



## **Entry and Inspection by members of Community Health Councils**

**88.** The contractor shall allow members of a Community Health Council authorised by or under regulation 20 of the Community Health Councils Regulations 2004(a) to enter and inspect the practice premises for the purpose of any of the Council's functions in accordance with the requirements of that regulation.

## **Entry and Inspection by the Commission for Healthcare Audit and Inspection and by the National Assembly for Wales**

**89.** The contractor shall allow persons authorised by the Commission for Healthcare Audit and Inspection and the National Assembly for Wales to enter and inspect the premises in accordance with section 66 and 73 of the Health and Social Care (Community Health and Standards) Act 2003 (rights of entry)(b).

## **PART 6**

### **COMPLAINTS**

#### **Complaints procedure**

**90.**-(1) The contractor shall establish and operate a complaints procedure to deal with any complaints in relation to any matter reasonably connected with the provision of services under the contract which shall -

- (a) until the coming into force of regulations in relation to complaints about general medical services made under section 113 of the Health and Social Care (Community Health and Standards) Act 2003 (complaints about health care) comply with the requirements in paragraphs 91 to 94 and 96;
- (b) on the coming into force of such regulations, comply with those regulations.

(2) The contractor shall take reasonable steps to ensure that patients are aware of -

- (a) the complaints procedure;
- (b) the role of the Local Health Board and other bodies in relation to complaints about services under the contract, and
- (c) their right to assistance with any complaint from independent advocacy services provided under section 19A of the Act(c).

(3) The contractor shall take reasonable steps to ensure that the complaints procedure is accessible to all patients.

#### **Making of Complaints**

**91.** A complaint may be made by or, with the patient's consent, on behalf of a patient, or former patient, who is receiving or has received services under the contract, or -

- (a) where the patient is a child -
  - (i) by either parent, or in the absence of both parents, the guardian or other adult who has care of the child,
  - (ii) by a person duly authorised by a local authority to whose care the child has been committed under the provisions of the Children Act 1989(d), or
  - (iii) by a person duly authorised by a voluntary organisation by which the child is being accommodated under the provisions of that Act;
- (b) where the patient is incapable of making a complaint, by a relative or other adult who has an interest in the patient's welfare.

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(a) SI 2004/ xxx(W. )

(b) 2003 c.43.

(c) Section 19A was inserted by section 12 of the Health and Social Care Act 2001 (c.18).

(d) 1989 c.41.

92. Where a patient has died a complaint may be made by a relative or other adult person who had an interest in the patient's welfare or, where the patient falls within paragraph 91(a)(ii) or (iii), by the authority or voluntary organisation.

### **Period for making complaints**

93.-(1) Subject to sub-paragraph (2), the period for making a complaint is -

- (a) six months from the date on which the matter which is the subject of the complaint occurred; or
- (b) six months from the date on which the matter which is the subject of the complaint comes to the complainant's notice provided that the complaint is made no later than 12 months after the date on which the matter which is the subject of the complaint occurred.

(2) Where a complaint is not made during the period specified in sub-paragraph (1), it shall be referred to the person nominated under paragraph 94(2)(a) and if that person is of the opinion that -

- (a) having regard to all the circumstances of the case, it would have been unreasonable for the complainant to make the complaint within that period; and
- (b) notwithstanding the time that has elapsed since the date on which the matter which is the subject matter of the complaint occurred, it is still possible to investigate the complaint properly

the complaint shall be treated as if it had been received during the period specified in sub-paragraph (1).

### **Further requirements for complaints procedures**

94.-(1) A complaints procedure shall also comply with the requirements set out in sub-paragraphs (2) to (6).

(2) The contractor must nominate -

- (a) a person (who need not be connected with the contractor and who, in the case of an individual, may be specified by the person's job title) to be responsible for the operation of the complaints procedure and the investigation of complaints; and
- (b) a partner, or other senior person associated with the contractor, to be responsible for the effective management of the complaints procedure and for ensuring that action is taken in the light of the outcome of any investigation.

(3) All complaints must be -

- (a) either made or recorded in writing;
- (b) acknowledged in writing within the period of two working days beginning with the day on which the complaint was made or, where that is not possible, as soon as reasonably practicable; and
- (c) properly investigated.

(4) Within the period of 20 working days beginning with the day on which the complaint was received by the person specified under sub-paragraph (2)(a) or, where that is not possible, as soon as reasonably practicable, the complainant must be given a written summary of the investigation and its conclusions.

(5) Where the investigation of the complaint requires consideration of the patient's medical records, the person specified under sub-paragraph (2) (a) must inform the patient or person acting on the patient's behalf if the investigation will involve disclosure of information contained in those records to a person other than the contractor or an employee of the contractor.

(6) The contractor must keep a record of all complaints and copies of all correspondence relating to complaints, but such records must be kept separate from patients' medical records.

### **Co-operation with investigations**

95.-(1) The contractor shall co-operate with -

- (a) any investigation of a complaint in relation to any matter reasonably connected with the provision of services under the contract undertaken by -
  - (i) the Local Health Board, and
  - (ii) the Commission for Healthcare Audit and Inspection,
  - (iii) the Assembly; and

- (b) any investigation of a complaint by an NHS body or local authority which relates to a patient or former patient of the contractor.

(2) In sub-paragraph (1) -

"NHS body" means a Local Health Board, (in England and Wales and Scotland) an NHS trust, an NHS foundation trust, a Strategic Health Authority, a Primary Care Trust, a Health Board, a Health and Social Services Board or a Health and Social Services Trust;

"local authority" means-

- (a) any of the bodies listed in section 1 of the Local Authority Social Services Act 1970 (local authorities)(constitution of councils)(a),
- (b) the Council of the Isles of Scilly, or
- (c) a council constituted under section 2 of the Local Government etc (Scotland) Act 1994 (constitution of councils)(b).

(3) The co-operation required by sub-paragraph (1) includes -

- (a) answering questions reasonably put to the contractor by the Local Health Board;
- (b) providing any information relating to the complaint reasonably required by the Local Health Board; and
- (c) attending any meeting to consider the complaint (if held at a reasonably accessible place and at a reasonable hour, and due notice has been given) if the contractor's presence at the meeting is reasonably required by the Local Health Board.

#### **Provision of information about complaints**

96. The contractor shall inform the Local Health Board, at such intervals as required, of the number of complaints it has received under the procedure established in accordance with this Part.

## **PART 7**

### **DISPUTE RESOLUTION**

#### **Local resolution of contract disputes**

97.-(1) Subject to sub-paragraph (3), in the case of any dispute arising out of or in connection with the contract, the contractor and the Local Health Board must make every reasonable effort to communicate and cooperate with each other with a view to resolving the dispute, before referring the dispute for determination in accordance with the NHS dispute resolution procedure (or, where applicable, before commencing court proceedings).

(2) Either the contractor or the Local Health Board may, if it wishes to do so, invite the Local Medical Committee for the area of the Local Health Board to participate in discussions which take place pursuant to sub-paragraph (1).

(3) In the case of a dispute which falls to be dealt with under the procedure specified in paragraph 36, sub-paragraph (1) does not apply where it is not practicable for the parties to attempt local resolution before the expiry of the period specified in paragraph 36(4).

#### **Dispute resolution: non-NHS contracts**

98.-(1) In the case of a contract which is not an NHS contract, any dispute arising out of or in connection with the contract, except matters dealt with under the complaints procedure pursuant to Part 6 of this Schedule, may be referred for consideration and determination to the Assembly,if-

- (a) the Local Health Board so wishes and the contractor has agreed in writing; or
- (b) the contractor so wishes (even if the Local Health Board does not agree).

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(a) 1970 c.42; section 1 was amended by the Local Government Act 1972 (c.70), section 195 and by the Local Government (Wales) Act 1994 (c.19), Schedule 10, paragraph 7.

(b) 1994 c.39.

- (2) In the case of a dispute referred to the Assembly under sub-paragraph (1) -
- (a) the procedure to be followed is the NHS dispute resolution procedure; and
  - (b) the parties agree to be bound by any determination made by the adjudicator.

### **NHS dispute resolution procedure**

99.-(1) Subject to sub-paragraph (2), the procedure specified in the following sub-paragraphs and paragraph 100 applies in the case of any dispute arising out of or in connection with the contract which is referred to the Assembly -

- (a) in accordance with section 4(3) of the 1990 Act (where the contract is an NHS contract); or
- (b) in accordance with paragraph 98(1) (where the contract is not an NHS contract).

(2) The procedure specified in this paragraph and paragraph 100 does not apply where a contractor refers a matter for determination in accordance with paragraph 36(1) of this Schedule, and in such a case the procedure specified in that paragraph shall apply instead.

(3) Any party wishing to refer a dispute as mentioned in sub-paragraph (1) shall send to the Assembly a written request for dispute resolution which shall include or be accompanied by -

- (a) the names and addresses of the parties to the dispute;
- (b) a copy of the contract; and
- (c) a brief statement describing the nature and circumstances of the dispute.

(4) Any party wishing to refer a dispute as mentioned in sub-paragraph (1) must send the request under sub-paragraph (3) within a period of three years beginning with the date on which the matter giving rise to the dispute happened or should reasonably have come to the attention of the party wishing to refer the dispute.

(5) Where the dispute relates to a contract which is not an NHS contract, the Assembly may determine the matter itself or, if the Assembly considers it appropriate, appoint a person or persons to consider and determine it(a).

(6) Before reaching a decision as to who should determine the dispute, either under sub-paragraph (5) or under section 4(5) of the 1990 Act, the Assembly shall, within the period of 7 days beginning with the date on which a matter was referred to it, send a written request to the parties to make in writing, within a specified period, any representations which they may wish to make about the matter.

(7) The Assembly shall give, with the notice given under sub-paragraph (6), to the party other than the one which referred the matter to dispute resolution a copy of any document by which the matter was referred to dispute resolution.

(8) The Assembly shall give a copy of any representation received from a party to the other party and shall in each case request (in writing) a party to whom a copy of the representations is given to make within a specified period any written observations which it wishes to make on those representations.

(9) Following receipt of any representations from the parties or, if earlier at the end of the period for making such representations specified in the request sent under sub-paragraph (6) or (8), the Assembly shall, if it decides to appoint a person or person to hear the dispute -

- (a) inform the parties in writing of the name of the person or persons whom it has appointed; and
- (b) pass to the person or persons so appointed any documents received from the parties under or pursuant to paragraph (3), (6) or (8).

(10) For the purpose of assisting the adjudicator in the consideration of the matter, the adjudicator may -

- (a) invite representatives of the parties to appear before the adjudicator to make oral representations either together or, with the agreement of the parties, separately, and may in advance provide the parties with a list of matters or questions to which the adjudicator wishes them to give special consideration; or
- (b) consult other persons whose expertise the adjudicator considers will assist in the consideration of the matter.

(11) Where the adjudicator consults another person under sub-paragraph (10)(b), the adjudicator shall notify the parties accordingly in writing and, where the adjudicator considers that the interests of any party might be substantially affected by the result of the consultation, the adjudicator shall give to the parties such opportunity as the adjudicator considers reasonable in the circumstances to make observations on those results.

(12) In considering the matter, the adjudicator shall consider -

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(a) Where the dispute relates to a contract which is an NHS contract, section 4(5) of the 1990 Act applies.

- (a) any written representations made in response to a request under sub-paragraph (6)(b), but only if they are made within the specified period;
- (b) any written observations made in response to a request under sub-paragraph (8), but only if they are made within the specified period;
- (c) any oral representations made in response to an invitation under sub-paragraph (10)(a);
- (d) the results of any consultation under sub-paragraph (10)(b); and
- (e) any observations made in accordance with an opportunity given under sub-paragraph (11).

(13) In this paragraph, "specified period" means such period as the Assembly shall specify in the request, being not less than 2, nor more than 4, weeks beginning with the date on which the notice referred to is given, but the Assembly may, if it considers that there is good reason for doing so, extend any such period (even after it has expired) and, where it does so, a reference in this paragraph to the specified period is to the period as so extended.

(14) Subject to the other provisions of this paragraph and paragraph 100 and to any agreement by the parties, the adjudicator shall have wide discretion in determining the procedure of the dispute resolution to ensure the just, expeditious, economical and final determination of the dispute.

### **Determination of dispute**

**100.**-(1) The determination of the adjudicator and the reasons for it, shall be recorded in writing and the adjudicator shall give notice of the determination (including the record of the reasons) to the parties.

(2) In the case of a contract referred for determination in accordance with paragraph 98(1), subsection (8) of section 4 of the 1990 Act shall apply as that subsection applies in the case of a contract referred for determination in accordance with subsection (3) of section 4 of that Act.

(3) In the case of a contract referred for determination in accordance with paragraph 98(1), subsection (5) of section 28W of the Act<sup>(a)</sup> shall apply as that subsection applies in the case of a contract referred for determination in accordance with subsection (3) of section 4 of the 1990 Act.

### **Interpretation of Part 7**

**101.**-(1) In this Part, "any dispute arising out of or in connection with the contract" includes any dispute arising out of or in connection with the termination of the contract.

(2) Any term of the contract that makes provision in respect of the requirements in this Part shall survive even where the contract has terminated.

## **PART 8**

### **VARIATION AND TERMINATION OF CONTRACTS**

#### **Variation of a contract: general**

**102.**-(1) Subject to Schedule 3 paragraphs 68(8), 69(8), 103, 104, and 115, and paragraph 3 of Schedule 7, no amendment or variation shall have effect unless it is in writing and signed by or on behalf of the Local Health Board and the contractor.

(2) In addition to the specific provision made in paragraphs 103(6), 104(6), and 115 the Local Health Board may vary the contract without the contractor's consent where it -

- (a) is reasonably satisfied that it is necessary to vary the contract so as to comply with the Act, any regulations made pursuant to that Act, or any direction given by the Assembly pursuant to that Act; and
- (b) notifies the contractor in writing of the wording of the proposed variation and the date upon which that variation is to take effect

and, where it is reasonably practicable to do so, the date that the proposed variation is to take effect shall be not

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(a) Section 28W was inserted into the Act by section 175(1) of the 2003 Act.

less than 14 days after the date on which the notice under paragraph (b) is served on the contractor.

### **Variation provisions specific to a contract with an individual medical practitioner**

**103.**-(1) If a contractor which is an individual medical practitioner proposes to practise in partnership with one or more persons during the existence of the contract, the contractor shall notify the Local Health Board in writing of -

- (a) the name of the person or persons with whom it proposes to practise in partnership; and
- (b) the date on which the contractor wishes to change its status as a contractor from that of an individual medical practitioner to that of a partnership which shall be not less than 28 days after the date upon which it has served the notice on the Local Health Board pursuant to this sub-paragraph.

(2) A notice under sub-paragraph (1) shall in respect of the person or each of the persons with whom the contractor is proposing to practise in partnership, and also in respect of itself as regards the matters specified in paragraph (c) -

- (a) confirm that is the person either -
  - (i) a medical practitioner, or
  - (ii) a person who satisfies the conditions specified in section 28S(2)(b)(i) to (iv) of the Act(a);
- (b) confirm that he or she is a person who satisfies the conditions imposed by regulations 4 and 5; and
- (c) state whether or not it is to be a limited partnership, and if so, who is to be a limited and who a general partner,

and the notice shall be signed by the individual medical practitioner and by the person, or each of the persons (as the case may be), with whom the medical practitioner proposing to practise in partnership.

(3) The contractor shall ensure that any person who will practise in partnership with it is bound by the contract, whether by virtue of a partnership deed or otherwise.

(4) If the Local Health Board is satisfied as to the accuracy of the matters specified in sub-paragraph (2) that are included in the notice, the Local Health Board shall give notice in writing to the contractor confirming that the contract shall continue with the partnership entered into by the contractor and its partners, from a date that the Local Health Board specifies in that notice.

(5) Where it is reasonably practicable, the date specified by the Local Health Board pursuant to sub-paragraph (4) shall be the date requested in the notice served by the contractor pursuant to sub-paragraph (1), or, where that date is not reasonably practicable, the date specified shall be a date after the requested date that is as close to the requested date as is reasonably practicable.

(6) Where a contractor has given notice to the Local Health Board pursuant to sub-paragraph (1), the Local Health Board ?

- (a) may vary the contract but only to the extent that it is satisfied is necessary to reflect the change in status of the contractor from an individual medical practitioner to a partnership; and
- (b) if it does propose to so vary the contract, it shall include in the notice served on the contractor pursuant to sub-paragraph (4) the wording of the proposed variation and the date upon which that variation is to take effect.

### **Variation provisions specific to a contract with two or more individuals practising in partnership**

**104.**-(1) Subject to sub-paragraph (4), where a contractor consists of two or more individuals practising in partnership in the event that the partnership is terminated or dissolved, the contract shall only continue with one of the former partners if that partner is -

- (a) nominated in accordance with sub-paragraph (3); and
- (b) a medical practitioner who meets the condition in regulation 4(2)(a),

and provided that the requirements in sub-paragraphs (2) and (3) are met.

(2) A contractor shall notify the Local Health Board in writing at least 28 days in advance of the date on which the contractor proposes to change its status from that of a partnership to that of an individual medical practitioner pursuant to sub-paragraph (1).

(3) A notice under sub-paragraph (2) shall -

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(a) Section 285 was inserted into the Act by section 175(1) of the 2003 Act.

- (a) specify the date on which the contractor proposes to change its status from that of a partnership to that of an individual medical practitioner;
  - (b) specify the name of the medical practitioner with whom the contract will continue, which must be one of the partners; and
  - (c) be signed by all of the persons who are practising in partnership.
- (4) If a partnership is terminated or dissolved because, in a partnership consisting of two individuals practising in partnership, one of the partners has died, sub-paragraphs (1), (2) and (3) shall not apply and ?
- (a) the contract shall continue with the individual who has not died only if that individual is a medical practitioner who meets the condition in regulation 4(2)(a); and
  - (b) that individual shall in any event notify the Local Health Board in writing as soon as is reasonably practicable of the death of his or her partner.
- (5) When the Local Health Board receives a notice pursuant to sub-paragraph (2) or (4)(b) it shall, acknowledge in writing receipt of the notice, and in relation to a notice served pursuant to sub-paragraph (2), the Local Health Board shall do so before the date specified pursuant to sub-paragraph (3)(a).
- (6) Where a contractor gives notice to the Local Health Board pursuant to sub-paragraph (2) or (4)(b), the Local Health Board may vary the contract but only to the extent that it is satisfied is necessary to reflect the change in status of the contractor from a partnership to an individual medical practitioner.
- (7) If the Local Health Board varies the contract pursuant to sub-paragraph (6), it shall notify the contractor in writing of the wording of the proposed variation and the date upon which that variation is to take effect.

#### **Termination by agreement**

**105.** The Local Health Board and the contractor may agree in writing to terminate the contract, and if the parties so agree, they shall agree the date upon which that termination should take effect and any further terms upon which the contract should be terminated.

#### **Termination by the contractor**

**106.**-(1) A contractor may terminate the contract by serving notice in writing on the Local Health Board at any time.

(2) Where a contractor serves notice pursuant to sub-paragraph (1), the contract shall, subject to sub-paragraph (3), terminate six months after the date on which the notice is served ("the termination date"), save that if the termination date is not the last calendar day of a month, the contract shall instead terminate on the last calendar day of the month in which the termination date falls.

(3) Where the contractor is an individual medical practitioner, sub-paragraph (2) shall apply to the contractor, save that the reference to " six months" shall instead be to "three months".

(4) This paragraph and paragraph 107 are without prejudice to any other rights to terminate the contract that the contractor may have.

#### **Late payment notices**

**107.**-(1) The contractor may give notice in writing (a "late payment notice") to the Local Health Board if the Local Health Board has failed to make any payments due to the contractor in accordance with a term of the contract that has the effect specified in regulation 22 and the contractor shall specify in the late payment notice the payments that the Local Health Board has failed to make in accordance with that regulation.

(2) Subject to sub-paragraph (3), the contractor may, at least 28 days after having served a late payment notice, terminate the contract by a further written notice if the Local Health Board has still failed to make the payments due to the contractor, and that were specified in the late payment notice served on the Local Health Board pursuant to sub-paragraph (1).

(3) If, following receipt of a late payment notice, the Local Health Board refers the matter to the NHS dispute resolution procedure within 28 days of the date upon which it is served with the late payment notice, and it notifies the contractor in writing that it has done so within that period of time, the contractor may not terminate the contract pursuant to sub-paragraph (2) until -

- (a) there has been a determination of the dispute pursuant to paragraph 100 and that determination permits the contractor to terminate the contract; or
- (b) the Local Health Board ceases to pursue the NHS dispute resolution procedure,

whichever is the sooner.

**Termination by the Local Health Board: general**

**108.** The Local Health Board may only terminate the contract in accordance with the provisions in this Part.

**Termination by the Local Health Board for breach of conditions in regulation 4**

**109.**-(1) The Local Health Board shall serve notice in writing on the contractor terminating the contract forthwith if the contractor is an individual medical practitioner and the medical practitioner no longer satisfies the condition specified in regulation 4(1).

(2) Where the contractor is -

- (a) two or more persons practising in partnership, and the condition specified in regulation 4(2)(a) is no longer satisfied; or
- (b) a company limited by shares, and the condition specified in regulation 4(3)(a) is no longer satisfied,

sub-paragraph (3) shall apply.

(3) Where sub-paragraph (2)(a) or (b) applies, the Local Health Board shall, subject to sub-paragraph (4) -

- (a) serve notice in writing on the contractor terminating the contract forthwith; or
- (b) serve notice in writing on the contractor confirming that the Local Health Board will allow the contract to continue, for a period specified by the Local Health Board of up to six months (the "interim period"), during which time the Local Health Board shall, with the consent of the contractor, employ or supply one or more general medical practitioners to the contractor for the interim period to assist the contractor in the provision of clinical services under the contract.

(4) Before deciding which of the options in sub-paragraph (3) to pursue, the Local Health Board shall, whenever it is reasonably practicable to do so, consult the Local Medical Committee (if any) for its area.

(5) If the contractor does not, pursuant to sub-paragraph (3)(b), consent to the Local Health Board employing or supplying a general medical practitioner during the interim period, the Local Health Board shall serve notice in writing on the contractor terminating the contract forthwith.

(6) If, at the end of the interim period, the contractor still falls within sub-paragraph (2)(a) or (b), the Local Health Board shall serve notice in writing on the contractor terminating the contract forthwith.

**Termination by the Local Health Board for the provision of untrue etc information**

**110.** The Local Health Board may serve notice in writing on the contractor terminating the contract forthwith, or from such date as may be specified in the notice if, after the contract has been entered into, it comes to the attention of the Local Health Board that written information provided to the Local Health Board by the contractor before the contract was entered into in relation to the conditions set out in regulation 4 and 5 (and compliance with those conditions) was, when given, untrue or inaccurate in a material respect.

**Other grounds for termination by the Local Health Board**

**111.**-(1) The Local Health Board may serve notice in writing on the contractor terminating the contract forthwith, or from such date as may be specified in the notice if ?

- (a) in the case of a contract with a medical practitioner, that medical practitioner;
- (b) in the case of a contract with two or more individuals practising in partnership, any individual or the partnership; and
- (c) in the case of a contract with a company limited by shares-
  - (i) the company,
  - (ii) any person legally and beneficially owning a share in the company, or



(iii) any director or secretary of the company,

falls within sub-paragraph (2) during the existence of the contract.

(2) A person falls within this sub-paragraph if -

- (a) it does not satisfy the conditions prescribed in section 28S(2)(b) or (3)(b) of the Act;
- (b) he, she or it is the subject of a national disqualification;
- (c) subject to sub-paragraph (3), he, she or it is disqualified or suspended (other than by an interim suspension order or direction pending an investigation or a suspension on the grounds of ill-health) from practising by any licensing body anywhere in the world;
- (d) subject to sub-paragraph (4), he or she has been dismissed (otherwise than by reason of redundancy) from any employment by a health service body unless before the Local Health Board has served a notice terminating the contract pursuant to this paragraph, he or she is employed by the health service body that dismissed him or her or by another health service body;
- (e) he, she or it is removed from, or refused admission to, a primary care list by reason of efficiency, fraud or unsuitability (within the meaning of section 49F(2), (3) and (4) of the Act respectively)(a) unless his, her or its name has subsequently been included in such a list;
- (f) he or she has been convicted in the United Kingdom of murder;
- (g) he or she has been convicted in the United Kingdom of a criminal offence other than murder and has been sentenced to a term of imprisonment of over six months;
- (h) subject to sub-paragraph (5), he or she has been convicted elsewhere of an offence which would if committed in England and Wales;
  - (i) constitute murder; or
  - (ii) constitute a criminal offence other than murder, and been sentenced to a term of imprisonment of over six months;
- (i) he or she has been convicted of an offence referred to in Schedule 1 to the Children and Young Persons Act 1933(b) offences against children and young persons with respect to which special provisions of this Act apply) or Schedule 1 of the Criminal Procedure (Scotland) Act 1995(c) (offences against children under the age of 17 years to which special provisions apply) ;
- (j) he, she or it has -
  - (i) been adjudged bankrupt or had sequestration of his or her estate awarded unless (in either case) he or she has been discharged or the bankruptcy order has been annulled;
  - (ii) been made the subject of a bankruptcy restrictions order or an interim bankruptcy restrictions order under Schedule 4A to the Insolvency Act 1986(d), unless that Order has ceased to have effect or has been annulled.
  - (iii) made a composition or arrangement with, or granted a trust deed for, his, her or its creditors unless he, she or it has been discharged in respect of it, or
  - (iv) been wound up under Part IV of the Insolvency Act 1986;
- (k) there is ?
  - (i) an administrator, administrative receiver or receiver appointed in respect of it, or
  - (ii) an administration order made in respect of it under Schedule B1 of the Insolvency Act 1986(e);
- (l) that person is a partnership and -
  - (i) a dissolution of the partnership is ordered by any competent court, tribunal or arbitrator, or
  - (ii) an event happens that makes it unlawful for the business of the partnership to continue, or for members of the partnership to carry on in partnership;

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(a) Section 49F was inserted into the Act by section 25 of the Health and Social Care Act 2001 (c.15) and amended by the National Health Service Reform and Health Care Professions Act 2002 (c.17) Schedule 2, paragraph 21.

(b) 1933 c 12 as amended by the Criminal Justice Act 1988 (1988 c.33), section 170, Schedule 15, paragraph 8 and Schedule 16, paragraph 16; Sexual Offences Act 1956 (1956 c.69), sections 48 and 51 and Schedules 3 and 4 and as modified by the Criminal Justice Act 1988, section 170(1), Schedule 15, paragraph 9.

(c) 1995 c.46.

(d) 1986 c.45. Schedule 4A was inserted by section 257 of and Schedule 2 to the Enterprise Act 2000 (c.40).

(e) Section 49F was inserted into the Act by section 25 of the Health and Social Care Act 2001 (c. 15) and amended by the National Health Service Reform and Health Care Professions Act 2002 (c.17) Schedule 2, paragraph 21.

(m) he or she has been -

- (i) removed from the office of charity trustee or trustee for a charity by an order made by the Charity Commissioners or the High Court on the grounds of any misconduct or mismanagement in the administration of the charity for which he or she was responsible or to which he or she was privy, or which he or she by his or her conduct contributed to or facilitated, or
- (ii) removed under section 7 of the Law Reform (Miscellaneous Provisions) (Scotland) Act 1990<sup>(a)</sup> (powers of the Court of Session to deal with management of charities), from being concerned in the management or control of any body;
- (n) he or she is subject to a disqualification order under the Company Directors Disqualification Act 1986<sup>(b)</sup>, the Companies (Northern Ireland) Order 1986<sup>(c)</sup> or to an order made under section 429(2)(b) of the Insolvency Act 1986 (failure to pay under county court administration order); or
- (o) he or she has refused to comply with a request by the Local Health Board for him or her to be medically examined on the grounds that it is concerned that he or she is incapable of adequately providing services under the contract and, in a case where the contract is with two or more individuals practising in partnership or with a company, the Local Health Board is not satisfied that the contractor is taking adequate steps to deal with the matter .

(3) A Local Health Board shall not terminate the contract pursuant to sub-paragraph (2)(c) where the Local Health Board is satisfied that the disqualification or suspension imposed by a licensing body outside the United Kingdom does not make the person unsuitable to be -

- (a) a contractor;
- (b) a partner, in the case of a contract with two or more individuals practising in partnership; or
- (c) in the case of a contract with a company limited by shares ?
  - (i) a person legally and beneficially holding a share in the company, or
  - (ii) a director or secretary of the company.

as the case may be.

(4) A Local Health Board shall not terminate the contract pursuant to sub-paragraph (2)(d)?

- (a) until a period of at least three months has elapsed since the date of the dismissal of the person concerned; or
- (b) if, during the period of time specified in paragraph (a), the person concerned brings proceedings in any competent tribunal or court in respect of the person's dismissal, until proceedings before that tribunal or court are concluded.

and the Local Health Board may only terminate the contract at the end of the period specified in paragraph (b) if there is no finding of unfair dismissal at the end of those proceedings.

(5) A Local Health Board shall not terminate the contract pursuant to sub-paragraph (2)(h) where the Local Health Board is satisfied that the conviction does not make the person unsuitable to be ?

- (a) a contractor;
- (b) a partner, in the case of a contract with two or more individuals practising in partnership; or
- (c) in the case of a contract with a company limited by shares?
  - (i) a person legally and beneficially holding a share in the company; or
  - (ii) a director or secretary of the company,

as the case may be.

**112.** The Local Health Board may serve notice in writing on the contractor terminating the contract forthwith or with effect from such date as may be specified in the notice if<sup>3/4</sup>

- (a) the contractor has breached the contract and as a result of that breach, the safety of the contractor's patients is at serious risk if the contract is not terminated; or
- (b) the contractor's financial situation is such that the Local Health Board considers that the Local Health

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(a) 1990 c.40.

(b) 1986 c.46 as amended by the Insolvency Act 2000 (c.39).

(c) S.I.1986/1032 (N.1.6).

Board is at risk of material financial loss.

### **Termination by the Local Health Board: remedial notices and breach notices**

**113.**-(1) Where a contractor has breached the contract other than as specified in paragraphs 109 to 112 and the breach is capable of remedy, the Local Health Board shall, before taking any action it is otherwise entitled to take by virtue of the contract, serve a notice on the contractor requiring it to remedy the breach ("remedial notice").

(2) A remedial notice shall specify <sup>3</sup>/<sub>4</sub>

- (a) details of the breach;
- (b) the steps the contractor must take to the satisfaction of the Local Health Board in order to remedy the breach; and
- (c) the period during which the steps must be taken ("the notice period").

(3) The notice period shall, unless the Local Health Board is satisfied that a shorter period is necessary to <sup>3</sup>/<sub>4</sub>

- (a) protect the safety of the contractor's patients; or
- (b) protect itself from material financial loss,

be no less than 28 days from the date that notice is given.

(4) Where a Local Health Board is satisfied that the contractor has not taken the required steps to remedy the breach by the end of the notice period, the Local Health Board may terminate the contract with effect from such date as the Local Health Board may specify in a further notice to the contractor.

(5) Where a contractor has breached the contract other than as specified in paragraphs 109 to 112 and the breach is not capable of remedy, the Local Health Board may serve notice on the contractor requiring the contractor not to repeat the breach ("breach notice").

(6) If, following a breach notice or a remedial notice, the contractor -

- (a) repeats the breach that was the subject of the breach notice or the remedial notice; or
- (b) otherwise breaches the contract resulting in either a remedial notice or a further breach notice,

the Local Health Board may serve notice on the contractor terminating the contract with effect from such date as may be specified in that notice.

(7) The Local Health Board shall not exercise its right to terminate the contract under sub-paragraph (6) unless it is satisfied that the cumulative effect of the breaches is such that the Local Health Board considers that to allow the contract to continue would be prejudicial to the efficiency of the services to be provided under the contract.

(8) If the contractor is in breach of any obligation and a breach notice or a remedial notice in respect of that default has been given to the contractor, the Local Health Board may withhold or deduct monies which would otherwise be payable under the contract in respect of that obligation which is the subject of the default.

### **Termination by the Local Health Board: additional provisions specific to contracts with two or more individuals practising in partnership and companies limited by shares**

**114.**-(1) Where the contractor is a company limited by shares, if the Local Health Board becomes aware that the contractor is carrying on any business which the Local Health Board considers to be detrimental to the contractor's performance of its obligations under the contract -

- (a) the Local Health Board shall be entitled to give notice to the contractor requiring that it ceases carrying on that business before the end of a period of not less than 28 days beginning on the day on which the notice is given ("the notice period"); and
- (b) if the contractor has not satisfied the Local Health Board that it has ceased carrying on that business by the end of the notice period, the Local Health Board may, by a further written notice, terminate the contract forthwith or from such date as may be specified in the notice.

(2) Where the contractor is two or more persons practising in partnership, the Local Health Board shall be entitled to terminate the contract by notice in writing on such date as may be specified in that notice where one or more partners have left the practice during the existence of the contract if in its reasonable opinion, the Local Health Board considers that the change in membership of the partnership is likely to have a serious adverse impact on the ability of the contractor or the Local Health Board to perform its obligations under the contract.

- (3) A notice given to the contractor pursuant to sub-paragraph (2) shall specify -
- (a) the date upon which the contract is to be terminated; and
  - (b) the Local Health Board's reasons for considering that the change in the membership of the partnership is likely to have a serious adverse impact on the ability of the contractor or the Local Health Board to perform its obligations under the contract.

### **Contract sanctions**

**115.**-(1) In this paragraph and paragraph 116, "contract sanction" means -

- (a) termination of specified reciprocal obligations under the contract;
- (b) suspension of specified reciprocal obligations under the contract for a period of up to six months; or
- (c) withholding or deducting monies otherwise payable under the contract.

(2) Subject to sub-paragraph (4), where the Local Health Board is entitled to terminate the contract pursuant to paragraph 110, 111, 112 or 113(4) or (6) or paragraph 114, it may instead impose any of the contract sanctions if the Local Health Board is reasonably satisfied that the contract sanction to be imposed is appropriate and proportionate to the circumstances giving rise to the Local Health Board's entitlement to terminate the contract.

(3) The Local Health Board shall not, under sub-paragraph (2), be entitled to impose any contract sanction that has the effect of terminating or suspending any obligation to provide, or any obligation that relates to, essential services.

(4) If the Local Health Board decides to impose a contract sanction, it must notify the contractor of the contract sanction that it proposes to impose, the date upon which that sanction will be imposed and provide in that notice an explanation of the effect of the imposition of that sanction.

(5) Subject to paragraph 116, the Local Health Board shall not impose the contract sanction until at least 28 days after it has served notice on the contractor pursuant to sub-paragraph (4) unless the Local Health Board is satisfied that it is necessary to do so in order to-

- (a) protect the safety of the contractor's patients; or
- (b) protect itself from material financial loss.

(6) Where the Local Health Board imposes a contract sanction, the Local Health Board shall be entitled to charge the contractor the reasonable costs of additional administration that the Local Health Board has incurred in order to impose, or as a result of imposing, the contract sanction.

### **Contract sanctions and the NHS dispute resolution procedure**

**116.**-(1) If there is a dispute between the Local Health Board and the contractor in relation to a contract sanction that the Local Health Board is proposing to impose, the Local Health Board shall not, subject to sub-paragraph (4), impose the proposed contract sanction except in the circumstances specified in sub-paragraph (2)(a) or (b).

(2) If the contractor refers the dispute relating to the contract sanction to the NHS dispute resolution procedure within 28 days beginning on the date on which the Local Health Board served notice on the contractor in accordance with paragraph 115(4) (or such longer period as may be agreed in writing with the Local Health Board), and notifies the Local Health Board in writing that it has done so, the Local Health Board shall not impose the contract sanction unless -

- (a) there has been a determination of the dispute pursuant to paragraph 100 and that determination permits the Local Health Board to impose the contract sanction; or
- (b) the contractor ceases to pursue the NHS dispute resolution procedure,

whichever is the sooner.

(3) If the contractor does not invoke the NHS dispute resolution procedure within the time specified in sub-paragraph (2), the Local Health Board shall be entitled to impose the contract sanction forthwith.

(4) If the Local Health Board is satisfied that it is necessary to impose the contract sanction before the NHS dispute resolution procedure is concluded in order to <sup>3</sup>/<sub>4</sub>

- (a) protect the safety of the contractor's patients; or
- (b) protect itself from material financial loss,

the Local Health Board shall be entitled to impose the contract sanction forthwith, pending the outcome of that procedure.

### **Termination and the NHS dispute resolution procedure**

**117.**-(1) Where the Local Health Board is entitled to serve written notice on the contractor terminating the contract pursuant to paragraph 110, 111, 112, or 113(4) or (6), the Local Health Board shall, in the notice served on the contractor pursuant to those provisions, specify a date on which the contract terminates that is not less than 28 days after the date on which the Local Health Board has served that notice on the contractor unless sub-paragraph (2) applies.

(2) This sub-paragraph applies if the Local Health Board is satisfied that a period less than 28 days is necessary in order to -

- (a) protect the safety of the contractor's patients; or
- (b) protect itself from material financial loss.

(3) In a case falling with sub-paragraph (1) where the exception in sub-paragraph (2) do not apply, where the contractor invokes the NHS dispute resolution procedure before the end of the period of notice referred to in sub-paragraph (1), and it notifies the Local Health Board in writing that it has done so, the contract shall not terminate at the end of the notice period but instead shall only terminate in the circumstances specified in sub-paragraph (4).

(4) The contract shall only terminate if and when ?

- (a) there has been a determination of the dispute pursuant to paragraph 100 and that determination permits the Local Health Board to terminate the contract; or
- (b) the contractor ceases to pursue the NHS dispute resolution procedure,

whichever is the sooner.

(5) If the Local Health Board is satisfied that it is necessary to terminate the contract before the NHS dispute resolution procedure is concluded in order to  $\frac{3}{4}$

- (a) protect the safety of the contractor's patients; or
- (b) protect itself from material financial loss,

sub-paragraphs (3) and (4) shall not apply and the Local Health Board shall be entitled to confirm, by written notice to be served on the contractor, that the contract will nevertheless terminate at the end of the period of the notice it served pursuant to paragraph 110, 111(1), 112, 113(4) or (6) or 114.

### **Consultation with the Local Medical Committee**

**118.**-(1) Whenever the Local Health Board is considering -

- (a) terminating the contract pursuant to paragraph 110, 111, 112, 113(4) or (6) or 114; or
- (b) imposing a contract sanction,

it shall, whenever it is reasonably practicable to do so, consult the Local Medical Committee for its area before it terminates the contract or imposes a contract sanction.

(2) Whether or not the Local Medical Committee has been consulted pursuant to sub-paragraph (1), whenever the Local Health Board imposes a contract sanction on a contractor or terminates a contract pursuant to this Part, it shall, as soon as reasonably practicable, notify the Local Medical Committee in writing of the contract sanction imposed or of the termination of the contract (as the case may be).

PART 9  
MISCELLANEOUS

**Clinical governance**

**119.**-(1) The contractor shall have an effective system of clinical governance.

(2) The contractor shall nominate a person who will have responsibility for ensuring the effective operation of the system of clinical governance.

(3) The person nominated under sub-paragraph (2) shall be a person who performs or manages services under the contract.

(4) In this paragraph "system of clinical governance" means a framework through which the contractor endeavours continuously to improve the quality of its services and safeguard high standards of care by creating an environment in which clinical excellence can flourish.

**Insurance**

**120.**-(1) The contractor shall at all times hold adequate insurance against liability arising from negligent performance of clinical services under the contract.

(2) The contractor shall not sub-contract its obligations to provide clinical services under the contract unless it has satisfied itself that the sub-contractor holds adequate insurance against liability arising from negligent performance of such services.

(3) In this paragraph -

- (a) "insurance" means a contract of insurance or other arrangement made for the purpose of indemnifying the contractor; and
- (b) a contractor shall be regarded as holding insurance if it is held by an employee of its in connection with clinical services which that employee provides under the contract or, as the case may be, sub-contract.

**121.** The contractor shall at all times hold adequate public liability insurance in relation to liabilities to third parties arising under or in connection with the contract which are not covered by the insurance referred to in paragraph 120(1).

**Gifts**

**122.**-(1) The contractor shall keep a register of gifts which -

- (a) are given to any of the persons specified in sub-paragraph (2) by or on behalf of -
  - (i) a patient,
  - (ii) a relative of a patient, or
  - (iii) any person who provides or wishes to provide services to the contractor or its patients in connection with the contract; and
- (b) have, in its reasonable opinion, an individual value of more than £100.00.

(2) The persons referred to in sub-paragraph (1) are -

- (a) the contractor;
- (b) where the contract is with two or more individuals practising in partnership, any partner;
- (c) where the contract is with a company -
  - (i) any person legally and beneficially holding a share in the company, or
  - (ii) a director or secretary of the company;
- (d) any person employed by the contractor for the purposes of the contract;
- (e) any general medical practitioner engaged by the contractor for the purposes of the contract;
- (f) any spouse of a contractor (where the contractor is an individual medical practitioner) or of a person specified in paragraphs (b) to (e); or

(g) any person (whether or not of the opposite sex) whose relationship with a contractor (where the contractor is an individual medical practitioner) or with a person specified in paragraphs (b) to (e) has the characteristics of the relationship between husband and wife.

(3) Sub-paragraph (1) does not apply where -

- (a) there are reasonable grounds for believing that the gift is unconnected with services provided or to be provided by the contractor;
- (b) the contractor is not aware of the gift; or
- (c) the contractor is not aware that the donor wishes to provide services to the contractor.

(4) The contractor shall take reasonable steps to ensure that it is informed of gifts which fall within sub-paragraph (1) and which are given to the persons specified in sub-paragraph (2)(b) to (g).

(5) The register referred to in sub-paragraph (1) shall include the following information -

- (a) the name of the donor;
- (b) in a case where the donor is a patient, the patient's National Health Service number or, if the number is not known, his address;
- (c) in any other case, the address of the donor;
- (d) the nature of the gift;
- (e) the estimated value of the gift; and
- (f) the name of the person or persons who received the gift.

(6) The contractor shall make the register available to the Local Health Board on request.

#### **Compliance with legislation and guidance**

123. The contractor shall -

- (a) comply with all relevant legislation and
- (b) have regard to all relevant guidance issued by the Local Health Board or the Assembly.

#### **Third party rights**

124. The contract shall not create any right enforceable by any person not a party to it.

### SCHEDULE 7

#### OUT OF HOURS SERVICES

Regulation 31

#### **Temporary arrangements for transfer of obligations and liabilities in relation to certain out of hours services**

1.-(1) In this Schedule -

"transferee doctor" means a person with whom an arrangement is made under sub-paragraph (2)

"out of hours arrangement" means an arrangement under sub-paragraph (2);

(2) Subject to the provisions of this Schedule, where a contractor is required to provide out of hours services under regulation 30 or 31 it may, until 31st December 2004, with the approval of the Local Health Board, make an arrangement with a person who holds a general medical services contract with the Local Health Board which includes the provision of out of hours services as if the enactments specified in sub-paragraph (4) subject to the modifications specified in sub-paragraph (5) were still in force.

(3) Subject to paragraph 2(3)(f) an arrangement made in accordance with sub-paragraph (2) shall, for so long as it continues, relieve the contractor of -

- (a) its obligations to provide out of hours services pursuant to regulation 30 or 31; and

(b) all liabilities under the contract in respect of those services.

(4) The enactments referred to in sub-paragraph (2) are paragraphs 18A to 18C of Schedule 2 to the National Health Service (General Medical Services) Regulations 1992(a) subject to the modifications in paragraph (5).

(5) The modifications referred to in sub-paragraph (4) are -

- (a) as if out of hours period had the meaning given in regulation 2 of these Regulations;
- (b) as if a transferee doctor meant a person referred to in sub-paragraph (2) (as modified by this sub-paragraph) who has undertaken to carry out the obligations of a contractor during all or part of the out of hours period in accordance with an out of hours arrangement referred to in that sub-paragraph;
- (c) as if the references to a doctor in paragraphs 18A(2) (except in head (b)), (3), (4), (5), (7)(b) to (g), (9)(a), (c) and (d), (10), (11) and (13), 18B(1)(2) and (4) to (7) and 18C were references to a contractor.
- (d) as if the references to terms of service in paragraph 18A(2), (7)(b) and (f) were references to a contract;
- (e) as if the reference to a doctor included in the medical list in paragraph 18A(2)(b) were replaced with a reference to a person who -
  - (i) holds a general medical services contract, or
  - (ii) provides personal medical services under section 28C of the Act;
- (f) as if the reference to a doctor ceasing to be included in a medical list in paragraph 18A(2C) was a reference to a person ceasing to hold a general medical services contract or to provide personal medical services;
- (g) as if the reference to services to patients with whom the doctor has made an arrangement under regulation 31 in paragraph 18A(4) was a reference to services which the doctor is required to provide under the contract;
- (h) as if the words "where his name is included in the list of another Health Authority or Primary Care Trust" were omitted from paragraph 18A(7)(a); and
- (i) as if sub-paragraphs (6), (7)(h), (14) and (15) of paragraph 18A were omitted.

(6) An arrangement referred to in sub-paragraph (2) shall terminate if the person with whom it is made ceases to hold a general medical services contract.

(7) A contractor may make more than one out of hours arrangement and may do so (for example) with different transferee doctors and in respect of different patients, different times and different parts of its practice area.

(8) A contractor may retain responsibility for, or make separate out of hours arrangements in respect of, the provision of maternity medical services to any patients under the contract and any separate out of hours arrangements it makes may encompass all or any part of the maternity medical services it provides.

(9) Nothing in this paragraph prevents a contractor from retaining or resuming its obligations in relation to named patients.

### **Application for approval of an out of hours arrangement**

2.-(1) An application to the Local Health Board for approval of an out of hours arrangement shall be made in writing and shall state -

- (a) the name and address of the proposed transferee doctor;
- (b) the periods during which the contractor's obligations under the contract are to be transferred;
- (c) how the proposed transferee doctor intends to meet the contractor's obligations during the periods specified under paragraph (b);
- (d) the arrangements for the transfer of the contractor's obligations under the contract to and from the transferee doctor at the beginning and end of the periods specified under paragraph (b);
- (e) whether the proposed arrangement includes the contractor's obligations in respect of maternity medical services; and
- (f) how long the proposed arrangements are intended to last and the circumstances in which the contractor's obligations under the contract during the periods specified under paragraph (b) would revert to it.

(2) The Local Health Board shall determine the application before the end of the period of 28 days beginning with the day on which the Local Health Board received it.

(3) The Local Health Board shall grant approval to a proposed out of hours arrangement if it is satisfied -

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(a) S.I. 1992/635 amended by S.I. 1996/702; S.I. 2002/1896 (W.197).



- (a) having regard to the overall provision of primary medical services provided in the out of hours period in its area, that the arrangement is reasonable and will contribute to the efficient provision of such services in the area;
- (b) having regard, in particular, to the interests of the contractor's patients, that the arrangement is reasonable;
- (c) having regard, in particular, to all reasonably foreseeable circumstances that the arrangement is practicable and will work satisfactorily;
- (d) that it will be clear to the contractor's patients how to seek primary medical services during the out of hours period;
- (e) where maternity medical services are to be provided under the out of hours arrangement, that they will be performed by a medical practitioner who has such medical experience and training as are necessary to enable him properly to perform such services; and
- (f) that if the arrangement comes to an end, the contractor has in place proper arrangements for the immediate resumption of its responsibilities,

and shall not refuse to grant approval without first consulting the Local Medical Committee (if any) for its area.

(4) The Local Health Board shall give notice to the contractor of its determination and, where it refuses an application, it shall send the contractor a statement in writing of the reasons for its determination.

(5) A contractor which wishes to refer the matter in accordance with the NHS dispute resolution procedure must do so before the end of the period of 30 days beginning with the day on which the Local Health Board's notification under sub-paragraph (4) was sent.

### **Effect of approval**

3. Where the Local Health Board has approved an out of hours arrangement with a transferee doctor the Local health Board and the transferee doctor shall be deemed to have agreed a variation of their contract which has the effect of including in it, from the date on which the out of hours arrangement commences and for so long as that arrangement is not suspended or terminated, the services covered by that arrangement and paragraph 102(1) of Schedule 6 shall not apply.

### **Review of approval**

4.-(1) Where it appears to the Local Health Board that it may no longer be satisfied of any of the matters referred to in paragraphs (a) to (f) of paragraph 2(3), it may give notice to the contractor that it proposes to review its approval of the out of hours arrangement.

(2) On any review under sub-paragraph (1), the Local health Board shall allow the contractor a period of 30 days, beginning with the day on which it sent the notice, within which to make representations in writing to the Local Health Board.

(3) After considering any representations made in accordance with sub-paragraph (2), the Local Health Board may determine to -

- (a) continue its approval;
- (b) withdraw its approval following a period of notice; or
- (c) if it appears to it that it is necessary in the interests of the contractor's patients, withdraw its approval immediately.

(4) Except in the case of an immediate withdrawal of approval, the Local Health Board shall not withdraw its approval without first consulting the Local Medical Committee (if any) for its area.

(5) Where the Local Health Board determines to withdraw its approval immediately, it shall notify the Local Medical Committee (if any) for its area.

(6) The Local Health Board shall give notice to the contractor of its determination under sub-paragraph (3).

(7) Where the Local Health Board withdraws its approval, whether immediately or on notice, it shall include with the notice a statement in writing of the reasons for its determination.

(8) A contractor which wishes to refer the matter in accordance with the NHS dispute resolution procedure must do so before the end of the period of 30 days beginning with the day on which the Local Health Board's notification under sub-paragraph (6) was sent.

(9) Where the Local Health Board determines to withdraw its approval following a period of notice, the withdrawal shall take effect at the end of the period of two months beginning with -

- (a) the date on which the notice referred to in sub-paragraph (6) was sent; or
- (b) where there has been a dispute which has been referred under the NHS dispute resolution procedure and the dispute is determined in favour of withdrawal, the date on which the contractor receives notice of the determination.

(10) Where the Local Health Board determines to withdraw its approval immediately, the withdrawal shall take effect on the day on which the notice referred to in sub-paragraph (6) is received by the contractor.

#### **Immediate withdrawal of approval other than following review**

5.-(1) The Local Health Board shall withdraw its approval of an out of hours arrangement immediately -

- (a) in the case of an arrangement with a person referred to in paragraph 1(2), if the person with whom it is made ceases to hold a general medical services contract with the Local Health Board which includes the provision of out of hours services; or
- (b) where, without any review having taken place under paragraph 4, it appears to the Local Health Board that it is necessary in the interests of the contractor's patients to withdraw its approval immediately,

and the withdrawal shall take effect on the day on which the notice is received by the contractor.

(2) The Local Health Board shall give notice to the contractor of a withdrawal of approval under sub-paragraph (1)(b) and (c) and shall include with the notice a statement in writing of the reasons for its determination.

(3) The Local Health Board shall notify the Local Medical Committee (if any) for its area of a withdrawal of approval under sub-paragraph 1(c).

(4) A contractor which wishes to refer a withdrawal of approval under sub-paragraph (1)(b) in accordance with the NHS dispute resolution procedure must do so before the end of the period of 30 days beginning with the day on which the Local Health Board's notification under sub-paragraph (2) was sent.

#### **Suspension or termination of an out of hours arrangement**

6. The contractor shall terminate an out of hours arrangement made under paragraph 1(2) with effect from the date of the taking effect of the withdrawal of the Local Health Board's approval of that arrangement under paragraph 4 or 5.

SCHEDULE 8  
CLOSURE NOTICE

<b>Application for List Closure</b>	
From: <i>Name of Contractor</i>	To: <i>Name of Local Health Board</i>
	Date:

In accordance with paragraph 29 of Schedule 6 to the National Health Service (General Medical Services Contracts) (Wales) Regulations 2004 on behalf of the above named contractor I/we wish to make a formal application for our list to be closed to new patients and assignments , as follows:

(1) Length of period of closure (which may not exceed 12 months and, in the absence of any agreement, shall be 12 months)	
(2) Date from which closure will take effect	
(3) Date from which closure will cease to have effect	
(4) Current number of registered patients	
(5) Reduction in terms of either a percentage of the number indicated in (4) above or an actual number of patients which would trigger a re-opening (or suspension of list closure) of the list	
(6) Increase in terms of either a percentage of the number indicated in (4) above or an actual number of patients which would trigger a re-closure (or lifting of the suspension of list closure) of the list	
(7) Any withdrawal or reduction of additional or enhanced services	

Signed.....

For [Name of contractor]

## SCHEDULE 9

Schedule 6, paragraph 40(2)

### LOCAL HEALTH BOARDS SPECIFIED FOR THE PURPOSES OF REPEATABLE PRESCRIBING

- |   |   |
|---|---|
| 1. Bwrdd Iechyd Lleol Ynys Môn                  | 1. Anglesey Local Health Board            |
| 2. Bwrdd Iechyd Lleol Gwynedd                   | 2. Gwynedd Local Health Board             |
| 3. Bwrdd Iechyd Lleol Caerdydd                  | 3. Cardiff Local Health Board             |
| 4. Bwrdd Iechyd Lleol Ceredigion                | 4. Ceredigion Local Health Board          |
| 5. Bwrdd Iechyd Lleol Sir Gaerfyrddin           | 5. Carmarthenshire Local Health Board     |
| 6. Bwrdd Iechyd Lleol Sir Ddinbych              | 6. Denbighshire Local Health Board        |
| 7. Bwrdd Iechyd Lleol Sir y Fflint              | 7. Flintshire Local Health Board          |
| 8. Bwrdd Iechyd Lleol Sir Fynwy                 | 8. Monmouthshire Local Health Board       |
| 9. Bwrdd Iechyd Lleol Sir Benfro                | 9. Pembrokeshire Local Health Board       |
| 10. Bwrdd Iechyd Lleol Powys                    | 10. Powys Local Health Board              |
| 11. Bwrdd Iechyd Lleol Abertawe                 | 11. Swansea Local Health Board            |
| 12. Bwrdd Iechyd Lleol Conwy                    | 12. Conwy Local Health Board              |
| 13. Bwrdd Iechyd Lleol Blaenau Gwent            | 13. Blaenau Gwent Local Health Board      |
| 14. Bwrdd Iechyd Lleol Pen-y-bont ar Ogwr       | 14. Bridgend Local Health Board           |
| 15. Bwrdd Iechyd Lleol Caerffili                | 15. Caerphilly Local Health Board         |
| 16. Bwrdd Iechyd Lleol Merthyr Tudful           | 16. Merthyr Tydfil Local Health Board     |
| 17. Bwrdd Iechyd Lleol Castell-nedd/Port Talbot | 17. Neath Port Talbot Local Health Board  |
| 18. Bwrdd Iechyd Lleol Casnewydd                | 18. Newport Local Health Board            |
| 19. Bwrdd Iechyd Lleol Rhondda Cynon Tâf        | 19. Rhondda Cynon Taff Local Health Board |
| 20. Bwrdd Iechyd Lleol Tor-faen                 | 20. Torfaen Local Health Board            |
| 21. Bwrdd Iechyd Bro Morgannwg                  | 21. Vale of Glamorgan Health Board        |
| 22. Bwrdd Iechyd Lleol Wrexham                  | 22. Wrexham Local Health Board            |

## SCHEDULE 10

Schedule 6, paragraph 76

### INFORMATION TO BE INCLUDED IN PRACTICE LEAFLETS

**A practice leaflet shall include -**

1. The name of the contractor.
2. In the case of a contract with a partnership -
  - (a) whether or not it is a limited partnership; and
  - (b) the names of all the partners and, in the case of a limited partnership, their status as a general or limited partner.
3. In the case of a contract with a company -
  - (a) the names of the directors, the company secretary and the shareholders of that company; and
  - (b) the address of the company's registered office.
4. The full name of each person performing services under the contract.
5. In the case of each health care professional performing services under the contract the health care professional's professional qualifications.
6. Whether the contractor undertakes the teaching or training of health care professionals or persons intending to become health care professionals.
7. The contractor's practice area, by reference to a sketch diagram, plan or postcode.
8. The address of each of the practice premises.
9. The contractor's telephone and fax numbers and the address of its website (if any).
10. Whether the practice premises have suitable access for disabled patients and, if not, the alternative arrangements for providing services to such patients.
11. How to register as a patient.
12. The right of patients to express a preference of practitioner in accordance with paragraph 18 of Schedule 6 and the means of expressing such a preference.
13. The services available under the contract.
14. The opening hours of the practice premises and the method of obtaining access to services throughout the core hours.
15. The criteria for home visits and the method of obtaining such a visit.
16. The consultations available to patients under paragraphs 5 and 6 of Schedule 6.
17. The arrangements for services in the out of hours period (whether or not provided by the contractor) and how the patient may contact such services.
18. If the services in paragraph 17 are not provided by the contractor, the fact that the Local Health Board referred to in paragraph 28 is responsible for commissioning the services.
19. The name and address of any local walk-in centre.
20. The telephone number of NHS Direct and details of NHS Direct online.
21. The method by which patients are to obtain repeat prescriptions.
22. If the contractor offers repeatable prescribing services, the arrangements for providing such services.

23. If the contractor is a dispensing contractor the arrangements for dispensing prescriptions.
24. How patients may make a complaint or comment on the provision of service.
25. The rights and responsibilities of the patient, including keeping appointments.
26. The action that may be taken where a patient is violent or abusive to the contractor or his staff or other persons on the practice premises or in the place where treatment is provided under the contract or other persons specified in paragraph 21(2) of Schedule 6.
27. Details of who has access to patient information (including information from which the identity of the individual can be ascertained) and the patient's rights in relation to disclosure of such information.
28. The name, address and telephone number of the Local Health Board which is a party to the contract and from whom details of primary medical services in the area may be obtained.

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